IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA	§	
ex rel. John King & Jane Doe	§	
and John King & Jane Doe,	§	
Individually	§	
	§	
STATE OF ILLINOIS, *ex rel.*	§	
John King & Jane Doe;	§	
STATE OF CALIFORNIA, *ex rel.*	§	**CIVIL ACTION NO. 06-2662**
John King & Jane Doe;	§	**TRANSFERRED FROM**
STATE OF FLORIDA *ex rel.*	§	**EASTERN DISTRICT OF**
John King & Jane Doe;	§	**PENNSYLVANIA**
STATE OF TENNESSEE *ex rel.*	§	**CIVIL ACTION NO. 03-3561**
John King & Jane Doe;	§	
STATE OF TEXAS *ex rel.*	§	
John King & Jane Doe;	§	**FILED UNDER SEAL**
COMMONWEALTH OF MASSACHUSETTS	§	
ex rel. John King & Jane Doe;	§	
STATE OF DELAWARE *ex rel.*	§	**PLAINTIFF'S FIFTH AMENDED**
John King & Jane Doe;	§	**COMPLAINT PURSUANT**
STATE OF NEVADA *ex rel.*	§	**TO 31 U.S.C. §§ 3729-3732,**
John King & Jane Doe;	§	**FEDERAL FALSE CLAIMS**
STATE OF LOUISIANA *ex rel.*	§	**ACT AND VARIOUS STATE**
John King & Jane Doe;	§	**FALSE CLAIMS ACTS, AND**
STATE OF HAWAII *ex rel.*	§	**PENDENT STATE CLAIMS**
John King & Jane Doe;	§	
DISTRICT OF COLUMBIA *ex rel.*	§	**JURY TRIAL DEMAND**
John King & Jane Doe;	§	
COMMONWEALTH OF VIRGINIA *ex rel.*	§	
John King & Jane Doe	§	
STATE OF GEORGIA *ex rel.*	§	
John King & Jane Doe;	§	
STATE OF INDIANA, *ex rel.*	§	
John King & Jane Doe;	§	
STATE OF MICHIGAN *ex rel.*	§	
John King & Jane Doe:	§	
STATE OF MONTANA *ex rel.*	§	
John King & Jane Doe;	§	
STATE OF NEW HAMPSHIRE *ex rel.*	§	
John King & Jane Doe;	§	
STATE OF NEW JERSEY *ex rel.*	§	
John King & Jane Doe;	§	

STATE OF NEW MEXICO *ex rel.*	§
John King & Jane Doe;	§
STATE OF NEW YORK *ex rel.*	§
John King & Jane Doe;	§
STATE OF OKLAHOMA *ex rel.*	§
John King & Jane Doe;	§
STATE OF RHODE ISLAND *ex rel.*	§
John King & Jane Doe;	§
STATE OF WISCONSIN *ex rel.*	§
John King & Jane Doe;	§
STATE OF CONNECTICUT *ex rel.*	§
John King & Jane Doe;	§
STATE OF NORTH CAROLINA *ex rel.*	§
John King & Jane Doe;	§
CITY OF CHICAGO *ex rel.*	§
John King & Jane Doe;	§
STATE OF COLORADO *ex rel.*	§
John King & Jane Doe;	§
STATE OF MARYLAND *ex rel.*	§
John King & Jane Doe;	§
STATE OF MINNESOTA *ex rel.*	§
John King & Jane Doe;	§
	§
Plaintiffs,	§
	§
VS.	§
	§
SOLVAY S.A.,	§
SOLVAY AMERICA, INC.,	§
SOLVAY PHARMACEUTICALS, INC.,	§
SOLVAY NORTH AMERICA, LLC,	§
SOLVAY PHARMACEUTICALS SARL, and	§
ABBOTT PRODUCTS, INC.	§
	§
Defendants.	§

PLAINTIFFS' FIFTH AMENDED COMPLAINT

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The United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago by and through qui tam Relators/Plaintiffs ("Relators") John King and Jane Doe, and Relators in their own right, bring this action under 31 U.S.C. §§ 3729–3732 (the "False Claims Act") to recover all damages, penalties and other remedies established by the False Claims Act, and would show the following:

I. INTRODUCTION

1. This suit concerns rampant fraud perpetrated against Medicaid, Medicare, and other federal healthcare programs through aggressive off-label marketing and kickback schemes relating to three drugs: Luvox, Aceon, and AndroGel. To expand and maintain its market share of these drugs, Solvay deliberately and deceptively marketed uses that had not been approved by the Food and Drug Administration ("FDA"), doled out kickbacks to doctors in exchange for prescriptions, and trained doctors to misstate diagnoses so that Medicaid and other federal healthcare programs would approve and pay for unapproved uses.

2. For a combined total of about fourteen years, Relators John King and Jane Doe worked as sales representatives and managers for Solvay, where they witnessed first-hand Solvay's company-wide policies of illegal kickbacks and off-label marketing of prescription drugs. John King worked at Solvay as a sales representative, Regional Marketing Manager and District Sales Manager, in locations including West Virginia, North Carolina, and Alabama, from 1992 until his termination in April of 2002. In those positions, he supervised sales

representatives marketing Luvox, Aceon, and AndroGel. Jane Doe was employed as a District Sales Manager within the Mid-South and Southwest regions from 1999 until her termination in 2002. She supervised sales representatives marketing Luvox, Aceon, and AndroGel, in various parts of Arkansas, Louisiana and Texas during the period at issue. In those positions, as directed by their supervisors, King and Doe enforced Solvay's policies of illegal promotion with regard to Luvox, Aceon, and AndroGel.

3. In comparison with pharmaceutical giants like Merck and Pfizer, Solvay was a company of intimate size. From 1996 to 2002 and beyond, Solvay was, through and through, from its sales force to the highest echelons of management, deeply committed to selling Luvox, Aceon, and AndroGel by any means. Those means included not only illegal off-label promotions, but also the dissemination of medical misinformation, fraudulent misrepresentations and omissions, kickbacks, and bribes, all in order to obtain prescriptions and win access to government formularies and reimbursement. Sales drove research and development decisions and trumped medical necessity. Claims for millions of dollars' worth of Luvox, AndroGel, and Aceon were paid by state Medicaid programs, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), Medicare Part D, and other federal healthcare programs as a direct result of Solvay's misdeeds.

II. PARTIES

4. Relator John King ("King") is a citizen of the United States and resident of the State of West Virginia.

5. Relator Jane Doe ("Doe") is a citizen of the United States and resident of the State of Florida.

6. Defendant Solvay S.A. is a corporation incorporated in Belgium. Its principal place of business is Rue du Prince Albert 33, B-1050 Brussels—Belgium. Solvay S.A. conducts extensive business in the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago.

7. Defendant Solvay America, Inc. is a corporation incorporated in the state of Delaware. Its principal place of business is 3333 Richmond Avenue, Houston Texas 77098. Defendant Solvay America, Inc. conducts extensive business in the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Solvay America, Inc. may be served through its registered agent, Corporation Service Company d/b/a CSC-Lawyers Inco, 211 E. 7th Street, Suite 620, Austin, Texas 78701.

8. Defendant Solvay North America, LLC is a limited liability corporation incorporated in the State of Delaware. Its principal place of business is 3333 Richmond Avenue, Houston Texas 77098. Defendant Solvay North America, LLC conducts extensive business in the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas,

and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Solvay North America, LLC may be served through its registered agent, Corporation Service Company d/b/a CSC-Lawyers Inco, 211 E. 7th Street, Suite 620, Austin, Texas 78701.

9. Defendant Solvay Pharmaceuticals Sarl is a corporation incorporated in Luxembourg. Solvay Pharmaceuticals Sarl conducts extensive business in the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago.

10. Defendant Solvay Pharmaceuticals, Inc. is a corporation incorporated in the State of Georgia. Defendant Solvay Pharmaceuticals, Inc. conducts extensive business in the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Solvay Pharmaceuticals, Inc. may be served through its registered agent, CT Corporations Systems, 1201 Peachtree Street, NE, Atlanta, Georgia, 30361.

11. Defendant Abbott Products, Inc. is a Georgia corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Abbott Products, Inc. conducts extensive business in the States of

California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. On February 16, 2010, Abbott Laboratories acquired Solvay Pharmaceuticals for EUR 4.5 billion ($6.2 billion). Abbott Laboratories' purchase of Solvay Pharmaceuticals has resulted in the substantial continuity of Solvay Pharmacetuicals' business. After the acquisition, Abbott Laboratories renamed Solvay Pharmaceuticals "Abbott Products, Inc." Abbott Products, Inc. has continued to produce and market Solvay Pharmaceuticals' products, such as AndroGel. Abbott Products, Inc. has retained some of Solvay Pharmaceuticals' employees in doing so. Abbott Products, Inc. may be served through its registered agent, CT Corporations Systems, 350 N. St. Paul St., Suite 2900. Dallas, Texas 75201.

III. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

12. All defendants referred to in paragraphs six through eleven are hereinafter referred to collectively as "Solvay" or "Defendants." Any and all acts alleged herein to have been committed by any or all of the Defendants were committed by said Defendants' officers, directors, employees, representatives or agents who at all times acted on behalf of their respective Defendant(s) for the purpose of benefiting the Defendants and within the course and scope of their employment.

13. The Defendants identified in paragraphs seven through nine are related entities sharing common employees, offices and business names such that they are joint and severally liable under legal theories of respondeat superior. Further, the past, present and continuing

relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity.

14. Solvay S.A. is a large multinational group of companies that engage or have engaged in a variety of business activities, including developing, marketing, and selling pharmaceutical products, all of which are or were accomplished through Solvay S.A.'s operating groups, subsidiaries, officers, directors, employees, and agents. Solvay S.A. contains both operating groups and regional companies, for the most part organized by location, including companies operating throughout the United States. The functions of these operating groups and regional companies overlap.

15. Solvay America, Inc. is a wholly-owned subsidiary of Solvay, S.A. and is or was the United States holding company for most of the North American subsidiaries of Solvay S.A., including Defendants Solvay North America, LLC and Solvay Pharmaceuticals, Inc.

16. Defendant Solvay North America, LLC is a wholly-owned subsidiary of Defendant Solvay America, Inc., which in turn is a wholly-owned subsidiary of Defendant Solvay, S.A. Solvay North America, LLC oversees and coordinates the activities of Solvay S.A.'s businesses in the United States, Canada and Mexico. Solvay North America, LLC provides financial, legal, lobbying, recruiting, compliance and other services to Solvay S.A.'s businesses in North America.

17. In 1986, Solvay S.A.'s executive committee considered acquiring Reid-Rowell and recommended the acquisition to Solvay America. Solvay America, along with other Solvay S.A. affiliates, paid part of the purchase price for Reid-Rowell. After the acquisition, Reid-

Rowell was renamed "Solvay Pharmaceuticals, Inc." because Solvay S.A.'s policy was to change the name to include "Solvay" if Solvay S.A. had fifty percent or more direct or indirect ownership of the subsidiary. Solvay Pharmaceuticals, Inc. ("Solvay Pharmaceuticals") was a wholly-owned subsidiary of Solvay America, Inc. In late 2004, Solvay S.A. reorganized its corporate structure, creating Solvay Pharmaceuticals SARL. After the reorganization, Solvay America sold its shares in Solvay Pharmaceuticals to Solvay Pharmaceuticals SARL.

18. Although each subsidiary had its own board and organization, each subsidiary nevertheless submits its annual budget for expenditures to Solvay S.A. Furthermore, all Solvay affiliates submit regular financial data through a database called Cheops in Belgium, most likely at Solvay S.A., to be grouped and placed into a global annual report, which is published in English and French. Some of these global annual reports can found on Solvay S.A.'s website at http://www.solvay-investors.com/services/library/annualreports/0,,4688-2-0,00.htm. All pharmaceutical affiliates are linked by internal email. The SOLID database includes research and development and manufacturing policies and research findings accessible by all Solvay pharmaceutical affiliates. It was Solvay Pharmaceuticals who wrote the global policies for the Solvay Group regarding research and manufacturing, in order to ensure that the policies would comply with the United States Food and Drug Administration ("FDA") protocols.

19. Since its acquisition, Solvay Pharmaceuticals is or has been a mere instrumentality or the alter ego of Solvay North America, Solvay America, Solvay Pharmaceuticals SARL and Solvay S.A. — without it the other defendants would have been forced to perform its services themselves. Solvay Pharmaceuticals, Solvay North America, Solvay America, Solvay Pharmaceuticals SARL and Solvay S.A. have common officers and

directors. For example, some members of the Executive Committee for Solvay S.A. based in Belgium are also directors, officers or board members of Solvay S.A.'s subsidiaries. Jacques Levy Morelle is the Vice Chairman of the Board of Directors for Solvay America, but is also the Group Corporate Secretary for Solvay S.A. Alois Michielson, the Chairman of the Board of Directors for Solvay S.A., shares the Vice Chairmanship of the Board of Directors for Solvay America with Mr. Morelle and was also on the Board of Directors for Solvay Pharmaceuticals. In 2001, Jurgen Ernst was Director and Chairman of the Board of Solvay Pharmaceuticals while simultaneously serving as a member of the Executive Committee of Solvay S.A. Further, in 2001, Whitson Sadler, Chief Executive Officer for Solvay America, and Phillip Uhrhan, Vice President of Finance for Solvay America, both served on the Board of Directors for Solvay Pharmaceuticals. In addition, in the same year, Whitson Sadler served on the Board of Directors for Solvay North America.

20. North America sales made up fifty percent of Solvay S.A.'s total pharmaceuticals sales for 2000. Unsurprisingly, Solvay S.A.'s executive management makes a practice of visiting its American subsidiaries.

21. Solvay S.A. and Solvay America, Inc. have exerted supervision, control, and dominion over Solvay Pharmaceuticals' activities, decisions, policies, and practices related to sales goals, sales tactics, compliance, regulatory affairs, medical affairs, research and development, human resources, legal issues, budget, accounting, employee compensation, employee benefits, employee expenses, manufacturing, and public relations. For example, District sales managers for Solvay Pharmaceuticals were briefed on Solvay S.A.'s business strategy as part of their yearly training. Solvay Pharmaceuticals' executive management also

spoke to physician speakers about Solvay S.A. and its goals. For example, in April 1999, Chris Offen, Senior Vice President of Commercial Operations for Solvay Pharmaceuticals, presented an overview of Solvay Pharmaceuticals and Solvay S.A. to the Cardiovascular Managed Care Advisory Board, a group of physicians paid to provide feedback to Solvay Pharmaceuticals on how to market its drugs.

22. In addition, at least until 2002, Solvay Pharmaceuticals' travel and entertainment corporate procedure required its employees, when traveling to Europe, to have the Solvay S.A. contact for the meeting arrange their hotel stays, as Solvay S.A. had negotiated rates at particular European hotels. This same travel and entertainment procedure required Solvay Pharmaceuticals employees to obtain approval for airplane chartering and purchase of any club memberships or season tickets from Solvay America, Inc. The procedure stated that mileage reimbursement for employees was set by the Vice President of Human Resources for Solvay America, Inc. Solvay America, Inc. also provided insurance coverage to Solvay Pharmaceuticals at least until 2002. In fact, Solvay is or was a "self insured" company as to the health insurance provided to all Solvay America employees regardless of subsidiary (pharmaceuticals, plastics, mining etc). All funds contributed by all Solvay companies and all employees across company boundaries were combined and co-mingled into the "Solvay America Welfare Benefits Plan," which provided health care coverage to those employed by Solvay America, including Solvay Pharmaceuticals employees. Solvay America provided the savings and pension plans offered to Solvay Pharmaceuticals employees in similar fashion.

23. Finally, Solvay Pharmaceuticals' executive management communicated frequently with Solvay America, Inc. and Solvay S.A. executive management on business issues,

including marketing campaigns for drugs and other business strategies. For example, in August 2000, David Neuberger, Senior Internal Auditor at Solvay America, sent a memorandum to Bob Solheim (Vice President of Finance and Administration), Ann Willmoth (Vice President of Sales), Barb Casey (Director of Training and Development) and Chip Dale (Controller and Chief Accounting Officer) at Solvay Pharmaceuticals and copied Morris Attaway, an internal auditor at Solvay America, and Phil Uhrhan, Vice President of Finance for Solvay America. That memorandum and accompanying audit information are attached as Exhibit 1 to Relators' Third Amended Complaint. Relators specifically retain and adopt all exhibits attached to their Third Amended Complaint and hereby incorporate them in this Fifth Amended Complaint for all purposes. Mr. Neuberger's letter described an audit of the expenses of twenty sales representatives in the Southwest region that revealed a high volume of questionable expenditures on physicians. *Id*. Mr. Neuberger challenged many of the expenses claimed by Solvay Pharmaceuticals' contract sales representatives as inappropriate given the American Medical Association's guidelines on gifts. *Id*. at KD00704. The expenses highlighted in his audit report include $452 in limousine rentals, Houston Astros tickets, forty tickets to *Les Miserables*, and gift certificates for restaurants, book stores, golf outings, and sporting goods. *Id*. at KD00706-07. The July 2000 memorandum concluded, "We question if these 'serve a genuine educational function' and are appropriate." *Id*. Solvay America's involvement in the conduct underlying expense reports by the sales force in marketing to physicians goes to the heart of controlling how Solvay Pharmaceuticals should market its drug, and the heart of this case.

24. Furthermore, Solvay S.A. and Solvay America often appeared on press releases with Solvay Pharmaceuticals in addressing issues relating to Luvox, Aceon, and AndroGel. For

example, on May 5, 1999, following the Columbine tragedy in Colorado, Solvay S.A. published and copyrighted a damage-control press release on the Solvay S.A. website after the public learned that Eric Harris had been prescribed and was taking Luvox at the time of the killings. Ex. 2. The press release claimed that no evidence linked Luvox to violent or suicidal behavior. *Id*. This press release proves that Solvay S.A. takes or took an active role in addressing liability issues that may arise from drugs made by its subsidiaries.

IV. JURISDICTION AND VENUE

25. Jurisdiction and venue are proper in this Court pursuant to the False Claims Act (31 U.S.C. § 3732(a)) because Relators' claims seek remedies on behalf of the United States for multiple violations of 31 U.S.C. § 3729 in the United States by all or any one of Defendants, some of which occurred in the Southern District of Texas, and because all or any one of Defendants transact other business within the Southern District of Texas. All defendants are subject to the general and specific personal jurisdiction of this Court. As a result of Solvay S.A.'s organizational structure, Solvay S.A. and Solvay Pharmaceutical Sarl have continuous and systematic contacts with the United States through its contacts with its American subsidiaries.

V. STATUTORY AND REGULATORY BACKGROUND

A. FDA's Role in the Regulation of Prescription Drugs

i. FDA Approval of Prescription Drugs

26. The FDA regulates human use of pharmaceutical drugs such as Aceon, Luvox, and AndroGel. Companies seeking to introduce new drugs for human use into interstate commerce must comply with FDA statutes and regulations, such as the Federal Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 301, *et seq*. Notably, the FDCA prohibits companies from distributing in interstate commerce any drugs that the FDA has not approved as safe and

effective. 21 U.S.C. § 355(a) and (b).

27. In order for a company to gain approval of a drug by the FDA, the company must first submit and receive approval of a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355. The company is required to include in its NDA all intended uses proposed for a new drug's labeling and to prove that the new drug is safe and effective for those uses. 21 U.S.C. § 355(b). To prove that the drug is safe and effective, the company must provide the FDA with data from scientifically sound clinical trials. The FDA will refuse approval of a new drug unless, on the basis of all information reviewed, it is demonstrated that a drug can safely accomplish its purported effect under the conditions proposed, and that the method of manufacture and distribution will properly preserve the drug for this purpose. 21 U.S.C. § 355(d).

28. In 1983**,** Congress passed the Orphan Drug Act to promote the development of pharmaceutical drugs for people with rare diseases or medical conditions by providing drug manufacturers with incentives, such as FDA funding of the clinical trials necessary for drug approval, certain tax breaks for expenses incurred in developing an orphan drug, and a seven-year period of marketing exclusivity to the first drug manufacturer to obtain FDA approval of the designated orphan drug. *See* Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (1983), codified at 21 U.S.C. §§ 360aa-360dd. Under the Orphan Drug Act, the FDA is required to grant orphan drug designation if the sponsor shows a "medically plausible basis for expecting the drug to be effective in the prevention, diagnosis, or treatment of that disease or condition." 21 C.F.R. § 316.25(a)(2). The fact that a drug has been designated as an orphan drug under the Orphan Drug Act does ***not*** mean that the drug is FDA-approved for the treatment of that indication. Solvay obtained an orphan drug designation to research the use of AndroGel in

treating wasting in patients diagnosed with Acquired Immunodeficiency Syndrome ("AIDS") and Human Immunodeficiency Virus ("HIV"). It never received FDA approval for this use, however, and thus this was an off-label use.

ii. FDA Regulation of Marketing of Prescription Drugs

29. When the FDA reviews an NDA and approves a drug for interstate distribution, that approval is only effective for the intended uses that were proposed in the NDA and described on the drug's FDA-approved label. Any use for a drug that was not proposed in the NDA and approved for the label by the FDA is referred to as "unapproved" or "off-label." 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000). Off-label use also includes the use of a drug granted orphan drug status under the Orphan Drug Act. Although physicians traditionally may legally prescribe a drug for an off-label use so long as the drug has been FDA-approved for some use, pharmaceutical companies are strictly prohibited from marketing a drug for an off-label use.

30. When a company markets a drug off-label, the drug becomes a new drug for that purpose and is considered "misbranded" in violation of 21 U.S.C. § 331; 21 U.S.C. § 352(f); 21 C.F.R. § 310.3 (h)(4) and (5); 65 Fed. Reg. 14286, 14286 (Mar. 16, 2000) ("[A]n approved new drug that is marketed for a 'new use' is also 'misbranded' under the FDCA, because the labeling of such a drug would not include 'adequate directions for use.'"). Section 352 of title 21 of the United States Code lists situations in which a drug is illegally misbranded, including but not limited to situations where: (1) the drug's labeling is "false or misleading in any particular;" (2) the drug's labeling does not bear adequate directions for use; or (3) the drug's labeling does not bear "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or

application, in such manner and form, as are necessary for the protection of users. . . ." *See* 21 U.S.C. § 352(a) and (f).

31. The term "labeling" encompasses the actual label attached to the drug's immediate container, as well as all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 C.F.R. § 321(m). The term has been construed to include a variety of drug company promotional materials, including booklets, pamphlets, and literature that is textually related to the product, even when disseminated without the presence of the drug. *See Kordel v. United States*, 335 U.S. 345, 349 (1948); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957). In determining if a drug's labeling or advertising is misleading and thus misbranded, one must examine "(among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article" as described by the labeling or advertising or the customary or usual use of the article. 21 U.S.C. § 321(n).

32. In order for a drug's labeling to include "adequate directions for use," the directions must allow a layman to use the drug safely and for its "intended use." *See* 21 C.F.R. § 201.5. The "intended use" of a drug refers to "the objective intent of the person legally responsible for the labeling of drugs." *See* 21 C.F.R. § 201.128. "The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article," and "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id*. Thus, if a manufacturer

promotes a drug for a use for which the label does not provide adequate directions for use or is otherwise false and misleading, misbranding has occurred, regardless of whether the drug is otherwise reimbursable for this use by the government health care program.

33. Over the years, the FDA has issued regulatory guidances to aid manufacturers in distinguishing between these illegal marketing strategies and legitimate non-promotional dissemination of information on off-label uses, by setting forth factors to determine whether a manufacturer's dissemination of information is actually promotional. These guidances make it clear that pharmaceutical manufacturers cannot use reprints, reference texts or Continuing Medical Education ("CME") programs as tools to promote off-label uses. *See* Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed. Reg. 52800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed. Reg. 52800 (Oct. 8, 1996); Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64074 (Dec. 3, 1997); Guidance for the Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 Fed. Reg. 1694-01 (Jan. 13, 2009). None of these guidances has changed the FDA's long-standing prohibition against marketing and promoting approved drugs for off-label uses.

B. Reimbursement of Prescription Drugs under Medicaid, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Plan, ADAPs, and Other Federal Healthcare Programs

i. Medicaid

34. Medicaid was established by Title XIX of the Federal Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled. In addition to

obtaining FDA approval, Solvay applied for and received Medicaid coverage for the three drugs in each of the fifty states, including the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia.

35. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *See* 42 U.S.C. § 1396a. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). States' FMAPs range between fifty percent and eighty-three percent.

a. Drug Coverage under Medicaid

36. As a general rule, to be reimbursable under a state's Medicaid program, a drug must be included on the state's formulary. Each state has its own means of deciding coverage, but federal law sets forth requirements states must meet in excluding or restricting coverage. *See* 42 U.S.C. § 1396r-8. A state may exclude or restrict coverage of a drug in four instances:

(1) the prescribed use is not for a medically accepted indication;
(2) the drug is on a list of drugs excluded by the state from Medicaid coverage;
(3) the drug manufacturer agreed to the restrictions on the drug in its rebate agreement with Medicaid; or
(4) the drug was excluded from the state's drug formulary.

31 U.S.C. § 1396r-8(d)(1). In addition, states may use prior authorization programs or preferred drug lists to control potential abuses of drugs, such as prescriptions for an indication that is not a

medically accepted indication. Uses that are not for "medically accepted indications" are not generally reimbursable by state Medicaid programs.

37. A "medically accepted indication" is a use that is listed in the labeling approved by the FDA or "the use of which is supported by one or more citations included or approved for inclusion in" one of the drug compendia identified by the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6). These compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(1)(B)(i). The United States Government and the states interpret "supported by" to require "some form of corroboration or validation." United States' Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiff's First Amended Complaint, *United States ex rel. Rost v. Pfizer, Inc*., 03-CV-11084, at p. 5 (May 16, 2008); *see also* Centers for Medicare and Medicaid Release No. 141 (May 4, 2006) ("The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II).").

38. Medicaid covers only reasonable and necessary medical services. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 U.S.C. § 1320c-5(a)(1).

39. States may establish drug formularies if they meet the following requirements. First, the formulary must be developed by a committee consisting of pharmacists, physicians and other qualified individuals appointed by the governor or by the state's Drug Use Review ("DUR") board consisting of healthcare professionals who have recognized knowledge and

expertise in the prescription, dispensing and monitoring of outpatient drugs, drug use review, and medical quality assurance. 42 U.S.C. § 1396r-8(d)(4)(A) and § 1396r-8(g)(3).

40. Second, the formulary must include every drug for which a manufacturer has entered into a Medicaid rebate agreement. 42 U.S.C. § 1396r-8(d)(4)(B). The state may, however, exclude a drug from the formulary if: (1) the drug is used for an on-label use -- or an off-label use that is a medically accepted indication based on compendia -- but the drug does not have a significant, clinically meaningful therapeutic advantage over other drugs on the formulary; and (2) the state provides a written explanation, which is available to the public, of why the drug is excluded. 42 U.S.C. § 1396r-8(d)(4)(C). Finally, any drugs excluded from the formulary must nevertheless be available to Medicaid enrollees under a prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D).

41. States generally have some method for drug manufacturers to request that its drug be added to the states' "preferred drug lists." In the majority of states, the Pharmaceutical and Therapeutics committee or the DUR board makes the decision on whether to add drugs to the state Medicaid program's preferred drug list. Generally, these committees announce that they will conduct a review of a class of drugs. At that time, a drug manufacturer may submit information to the committees to be considered for the drug list. A minority of states, such as Indiana, Montana, Nevada and Texas, require drug manufacturers to submit an application to be placed on the drug list. As part of the Texas application, drug manufacturers are required to expressly certify compliance with all laws, regulations and rules applicable to the Medicaid program, including the federal and state Anti-Kickback statutes.

42. Third, each state is required to develop a drug use review program to continually assure that prescriptions are appropriate, medically necessary, and unlikely to cause adverse medical results. The drug use review program must be designed to use data on drug use to educate physicians and pharmacists to identify patterns of fraud, abuse, gross overuse, inappropriate/medically unnecessary care, and potentially severe adverse drug reactions, with the aim of reducing such patterns. In assessing drug use data, the drug use review program must "assess data on drug use against predetermined standards," using peer-reviewed literature and the Medicaid-approved compendia as the source for these standards. 42 U.S.C. § 1396r-8(g)(1) and (2).

b. Role of Prior Authorization and ICD-9 Coding in Drug Reimbursement

43. Most states require prior authorization for drugs that are not listed on their preferred drug lists or formularies. To obtain prior authorization, and consequently Medicaid coverage for a drug requiring prior authorization, most states require a physician to state why the drug is necessary and provide the pertinent diagnosis, either written out or by using "ICD-9 codes," a coding system used by Medicaid to numerically designate a diagnosis or diagnoses. Some states' prior authorization forms also require a physician to certify that the drug is medically justified or that the information on the form is accurate and complete. Upon information and belief, certain state Medicaid programs will reimburse for pharmaceutical drugs only if the drug corresponds with a specific diagnosis of the patient, designated by an ICD-9 code recorded by the patient's physician.

44. All three of Solvay's drugs involved in this case (Luvox, Aceon, and AndroGel) require prior approval in some states. All three drugs were promoted for off-label uses,

including many uses that are not eligible for reimbursement because they appear in no approved compendium.

ii. Medicare Part D

45. Medicare Part D is a federal program meant to subsidize the costs of prescription drugs for Medicare beneficiaries. It was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and went into effect on January 1, 2006. Part D only covers prescription drugs and will not assist with any other medical procedure (i.e. X-rays, doctor visits, etc.). Among those individuals eligible for Medicare Part D are individuals with dual-eligibility, i.e., beneficiaries enrolled in both Medicare and Medicaid, who prior to 2006 had received outpatient drug benefits though Medicaid. Although Medicare Part D is a component of Medicare, each of the fifty states and the District of Columbia are required to make a contribution to the United States government to defray a portion of the cost of Medicare Part D for beneficiaries whose Medicaid drug coverage has been assumed by Medicare Part D. 42 C.F.R. § 423.910(a) (2008).

46. A Medicare beneficiary enrolled in Medicare Part D chooses a Prescription Drug Plan (PDP), which is administered by a private insurance company, or "sponsor," based upon the beneficiary's specific drug requirements. The standard costs structure makes beneficiaries responsible for certain costs, which may include a monthly premium, an annual deductible, and coinsurance.

47. In 2008, for example, the standard drug benefit had a beneficiary deductible of $275. In the initial phase of the Part D benefit, after beneficiaries paid the deductible, they contributed 25 percent coinsurance toward their drug costs and the plan paid the remaining 75 percent until combined beneficiary and plan payments reached $2,510. After combined

payments reached $2,510, beneficiaries entered the coverage gap phase of the benefit, or "donut-hole," in which they were responsible for 100 percent of their drug costs. The catastrophic coverage phase began when a beneficiary's out-of-pocket costs reached $4,050. This amount included a beneficiary's deductible and coinsurance payments. Once beneficiaries reached $4,050 in out-of-pocket costs, they contributed approximately 5 percent in coinsurance toward their drug costs. Of the remaining 95 percent of drug costs, the Part D sponsors are responsible for approximately 15 percent while Medicare pays 80 percent.

48. Before the beginning of the plan year, sponsors are required to submit a bid for each plan that they intend to offer. The bid is an estimate of the average costs to provide the basic benefit per beneficiary. Throughout the year, the Centers for Medicare & Medicaid Services (CMS) makes prospective payments to sponsors for three subsidies based on sponsors' approved bids. These subsidies are: (1) the direct subsidy, (2) the reinsurance subsidy, and (3) the low-income cost-sharing subsidy. The direct subsidy, together with beneficiary premiums, is designed to cover the sponsor's cost of providing the benefit to each beneficiary. The reinsurance subsidy covers the Federal Government's share of drug costs for beneficiaries who have reached catastrophic coverage. The low-income cost-sharing subsidy covers the Federal Government's portion of the cost-sharing payments for certain low-income beneficiaries. At the end of the plan year, CMS reconciles these prospective payments with the actual costs incurred by the plan sponsors.

49. All Part D plan sponsors submit data and information necessary for CMS to determine and make payment. Every time a beneficiary fills a prescription covered under Part D, plan sponsors must submit a summary called the prescription drug event (PDE) record. The PDE

record contains drug cost and payment data that enable CMS to administer the Part D benefit. Part D plan sponsors submit one PDE record each time a Part D covered drug is dispensed to its enrollees, even for those events in which enrollees have 100 percent cost sharing (i.e., they are in the coverage gap or deductible phase).

50. CMS uses the National Council for Prescription Drug Programs industry standard for collecting PDE data. The PDE data contain information on the beneficiary, plan, pharmacy, and prescribing physician, as well as information about the event, including the date, quantity dispensed, number of days supplied, national drug code, control number, and the amount reimbursed to the pharmacy by the plan.

51. Medicare covers only reasonable and necessary medical services. *See, e.g.,* 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 U.S.C. § 1320c-5(a)(1).

52. Part D covered drugs are defined as drugs available only by prescription, used and sold in the United States and used for a medically accepted indication, biological products, insulin and vaccines. *See* 42 C.F.R. § 423.100. Medicare Part D's definition of a "medically accepted indication" is the same as Medicaid's: it is a use that is approved under the Federal Food, Drug, and Cosmetic Act, or "is supported by one or more citations included or approved for inclusion in" one of the drug compendia identified by the Medicaid statute (i.e., American Hospital Formulary Service Drug Information, DRUGDEX, and United States Pharmacopeia-Drug Information (or its successor publications)). *See* 42 C.F.R. § 423.100, 42 U.S.C. §§ 1396r-8 (g)(1)(B)(i) and (k)(6). As stated above, the United States Government interprets "supported by" to require "some form of corroboration or validation."

53. Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for "medically accepted indications." Some Part D sponsors use prior authorization programs to ensure drugs are being used for medically-accepted indications. AndroGel is commonly listed on PDP formularies for Medicare Part D and is reimbursable under many Medicare Part D plans across the country.

iii. CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Plan, and ADAPs

54. In addition to Medicaid and Medicare Part D, the federal and state governments reimburse a portion of the cost of prescription drugs under several other federal and state health care programs, including but not limited to CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, and ADAPs. These programs cover only reasonable and necessary medical services. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 U.S.C. § 1320c-5(a)(1).

55. The Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") and TRICARE, a continuation of CHAMPUS, are federally funded uniformed services health care programs for active duty and retired service members, members of the National Guard and Reserve, service members' families, survivors of service members, and certain former spouses of service members. The Civilian Health and Medical Program of the Department of Veterans Affairs ("CHAMPVA"), is a federally funded healthcare program for the families and survivors of veterans who have been rated permanently and totally disabled for a service-connected disability and for the survivors of a military member who died in the line of duty, not due to misconduct. The Federal Employees Health Benefit Plan is administered by the Office of Personnel Management and provides health insurance for federal employees, retirees,

and survivors. Coverage of prescription drugs under these programs is similar to coverage under the Medicaid program. *See, e.g.*, 32 C.F.R. §§ 199.2 and 199.4(g)(15)(i); TRICARE Policy Manual 6010.54-M, Chapter 8, Section 9.1(B)(2) (August 2002); CHAMPVA Policy Manual, Chapter 2, Section 22.1, Art. II.

56. Title II of the Ryan White Comprehensive AIDS Resources Emergency Act (the "CARE Act") authorizes the creation of state AIDS Drug Assistance Programs ("ADAPs"). ADAP is a federal program that allows for an expansion of Medicare and Medicaid coverage. In addition to allowing states to create their own programs, ADAP provides more federal funding for states to expand eligibility to include a greater number of AIDS victims and ensure that HIV-positive uninsured and under-insured individuals have access to pharmaceutical (drug) therapies. The goal of ADAP is to make available drug treatments that can reliably be expected to increase the duration and quality of life of people living with HIV, while ensuring that ADAP is used only after all other potential payer options are exhausted. Coverage of prescription drugs under ADAPs is the same as Medicaid. *See* Veterans' Health Care Act of 1992, Pub. L. No. 102-585, § 602 (November 1992).

C. Prohibition of Kickbacks Associated with Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employee Health Benefit Plan, and ADAPs Prescriptions

i. Federal Anti-Kickback Statute

57. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), make it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" is broadly defined to include

anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program. *See* Department of Health and Human Services, Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23734, 23737 (May 5, 2003). Pursuant to the Patient Protection and Affordable Care Act, a violation of the Anti-Kickback Statute is a false or fraudulent claim for purposes of the FCA. *See* P.L. 111-148, § 6402, codified as 42 U.S.C. § 1320a-7b(g).

58. The purpose of the Anti-Kickback Statute is to prohibit such remuneration in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089 (proposed Jan. 23, 1989) (to be codified 42 C.F.R. pt. 1001) ("[I]t is necessary for the fiscal integrity of the Medicare and Medicaid programs to assure that physicians exercise sound, objective medical judgment when controlling admittance [of new drugs and medical devices] to . . ." the medical marketplace.).

59. Paying kickbacks taints an entire prescription, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk. Any defendant convicted under the statute is automatically barred from participating in federal and federally-funded healthcare programs.

ii. OIG, PhRMA, AMA and ACCME's Guidelines on the Manufacturer-Doctor Relationship and Behaviors that Violate the Anti-Kickback Statute

60. Recognizing that the Anti-Kickback Statute has been applied broadly, the OIG has acknowledged that liability under the statute will ultimately turn on intent. *See* Department of Health and Human Services, Office of Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). In order to assist pharmaceutical manufacturers, the OIG issued a guidance in May 2003 that not only stated its interpretation of the Anti-Kickback statute, but also highlighted activities that may give rise to liability under the statute. *See id.* The OIG Guidance also directed drug manufacturers to review the PhRMA Code of Interactions with Healthcare Professionals ("the PhRMA Code"), the Accreditation Council for Continuing Medical Education ("ACCME") standards relating to CMEs, and an ethical opinion issued in June 1992 and amended in April 2001 by the American Medical Association ("AMA") stating its guidelines to govern doctors' acceptance of gifts from pharmaceutical manufacturers. *See* AMA Opinion 8.061 (1992, amended 2001); PhRMA Code (2003); ACCME Standards (2004). All of these industry guidelines draw plain lines of demarcation for acceptable and unacceptable behavior under the Anti-Kickback statute.

61. The OIG's Guidance addressed specific practices commonly arising in the relationship between a drug manufacturer and physicians that present problems. *Id*. at 23738. Of particular concern to the OIG were "preceptorships," educational and research funding, CMEs, consulting and advisory arrangements, and gifts of more than trivial value to physicians, such as entertainment, recreation, travel, and meals. *Id*. The OIG was also concerned about payments to physicians to: 1) listen to sales representatives market their drugs, 2) access marketing web sites, or 3) perform "research" for drug manufacturers. *Id*.

62. The AMA, PhRMA and ACCME guidelines have suggested similar limits on pharmaceutical activities. Where the three guidelines share the same perspectives on improper activities, one can presume these activities are likely to violate the federal Anti-Kickback statute.[1]

63. The issuance of these guidelines by the OIG, AMA, PhRMA and ACCME, in addition to the enactment of the Anti-Kickback Statute itself, demonstrates that federal and state health care programs consider compliance with the Anti-Kickback Statute a prerequisite to receiving or retaining reimbursement payments from Medicaid, Medicare Part D, and other federal health care programs.

VI. SOLVAY'S SCHEME TO SELL LUVOX, ACEON, AND ANDROGEL THROUGH OFF-LABEL MARKETING AND ILLEGAL KICKBACKS

A. Off-Label Marketing Strategies and False Claims

64. As described below, Solvay engaged in a nationwide off-labeling scheme that not only violated the FDA prohibitions against marketing off-label uses of drugs, but also violated the Anti-Kickback statute. Two of the drugs, AndroGel and Luvox, were each indicated only for one rare condition — Solvay's promotion of these two drugs was *predominantly* off-label. The third drug, Aceon, arrived as a latecomer in an extremely crowded field, and relied on deceptive off-label claims to distinguish itself. As a result of this nationwide scheme, Solvay reaped profits far beyond those it would have achieved from legitimate promotion.

[1] The three guidelines all address several pharmaceutical activities, such as gifts, entertainment, conferences, CMEs, and consultants. The ACCME standards address only CME activities.

i. Luvox (Fluvoxamine)

a. Luvox's Regulatory History and Approved Label

65. Fluvoxamine, known in the United States by the trade name Luvox, was first submitted to the FDA for approval in 1983. The FDA considered seventy-one separate studies and 1,172 subjects treated with fluvoxamine over an eight-year period before, in 1986, it sent the sponsor a "not-approvable letter" because the studies did not demonstrate the drug's efficacy.[2] Ex. 3 at 6-7. Solvay decided to investigate a possible Obsessive Compulsive Disorder ("OCD") indication next, and in 1991 filed an NDA for that use. In the meantime, Prozac, a selective serotonin re-uptake inhibitor ("SSRI") like Luvox, had received FDA approval for depression in 1987 and was rapidly becoming a blockbuster drug. Solvay filed a new NDA for Luvox for use in treating depression in 1993 while the OCD NDA was pending.

66. In December of 1994, the FDA approved Luvox's NDA for OCD, enabling Luvox to enter the United States market. The approved label specified:

> LUVOX® tablets are indicated for the treatment of obsessions and compulsions in patients with Obsessive Compulsive Disorder (OCD), as defined in the DSM-III-R. The obsessions or compulsions cause marked distress, are time-consuming, or significantly interfere with social or occupational functioning … Obsessive Compulsive Disorder is characterized by recurrent and persistent ideas, thoughts, impulses or images (obsessions) that are ego-dystonic and/or repetitive, purposeful, and intentional behaviors (compulsions) that are recognized by the person as excessive or unreasonable.

Ex. 4 at KD00932.[3]

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[2] Fluvoxamine did succeed in winning approval for depression in a number of European countries, beginning in 1983, and data surrounding use in those countries was available to the FDA.

[3] The DSM IIIR is the third revised version of the American Psychiatric Association's Diagnostic and Statistical Manual, issued in 1987 and used to diagnose mental health disorders. The label was later updated to refer to the fourth edition. *See* DSM-IV (Section 300.3) (1994). The label has always defined OCD by means of these very specific DSM requirements.

67. On April 12, 1994, Dr. Leber, Director of the FDA's Division of Neuropharmacological Drug Products informed three Solvay employees, Dr. Greg Perkins, Vice President of Regulatory Affairs, Dr. Vincent Houser, Director, CNS division, and Don Ruggirello, Senior Scientist, Regulatory Affairs, that the studies submitted in support of depression did not demonstrate Luvox's efficacy in treating depression, and further, that Solvay's "revised clinical depression program" would not win a depression indication. He outlined a different protocol and warned that "both studies must robustly document the effectiveness of LUVOX®." Solvay balked at the cost in a response to the FDA in August 1994, and requested an additional teleconference, which request the FDA denied. Solvay continued to propose new protocols for further study, to which the FDA responded, with the last letter from the FDA, dated August 16, 1996, questioning Solvay's test strategy for the drug. On information and belief, Solvay either never went forward with the trials, or else they proved a failure.

68. Approximately 2.2 million American adults age eighteen and older, or about one percent of people in this age group in a given year, have OCD, according to the National Institutes of Mental Health (NIMH); it is believed that these potential patients are, moreover, especially likely to conceal their symptoms and evade diagnosis and treatment. In contrast to that figure, approximately 18.8 million American adults, or about 9.5 percent of the U.S. population age eighteen and older in a given year, have a depressive disorder, according to the NIMH. The narrow FDA approval was a great disappointment to Solvay.

69. Solvay management never informed its sales force that the FDA had denied Luvox an indication for depression, nor that the company had abandoned further study of Luvox for depression. The sales force was ignorant of these events.

70. In fact, Solvay's sales force was assured that Solvay had so far failed to obtain a depression indication for Luvox only because of what was described as a technicality: the "Cytochrome P450" side effect. Luvox, like the antihistamine Seldane, used in conjunction with certain other drugs, such as Xanax, affects the 3A4 pathway in the liver. Luvox inhibits the Cytochrome P450 enzyme from metabolizing substances, such as caffeine, haloperidol (Haldol), diazepam (Valium), theophylline (used to treat asthma and respiratory diseases), and alprazolam (Xanax). This inhibition can then cause the drug to accumulate in the bloodstream, potentially leading to heart arrhythmia, cardiac arrest, and even death.

71. The side effect was serious enough to strip Seldane of its FDA approval. Nevertheless, shortly after receiving the FDA's decision, Jack Redmond, Group Product Manager for the Mental Health Marketing Team, and Steve Jennings, Business Director for Cardiovascular and Mental Health Marketing, told the entire Mental Health sales force that the FDA was unconcerned about the Cytochrome P450 side effect and that the FDA was "thrilled" to have another SSRI on the market that could fight not only OCD but depression and other diseases, especially given Luvox's "favorable side effect profile." Redmond and Jennings assured the team that if Prozac and other SSRIs had been applying for approval only now, they would have received the same warnings and perhaps been approved for a limited indication. The sales force was encouraged to share this message with doctors, and did so.

72. As years went by, challenges to Luvox's claims of safety and efficacy mounted, casting doubt on the company's version of the reasons for Luvox's failure to obtain a depression indication. The company instructed the sales force that whenever doctors challenged them on Luvox's efficacy in treating depression, representatives were to respond that further clinical data

on depression was unnecessary because all SSRI's worked the same way in the body, and because Luvox had been sufficiently tested and used in Europe.

73. In 1997, Solvay obtained a limited approval for Luvox to treat OCD in children. Later the same year, the FDA placed Solvay on its Application Integrity Policy ("AIP") list. Placement on the FDA's AIP list is a punitive measure that the FDA can impose upon learning of a company's suspected wrongdoing regarding the FDA drug application process. For the period of time that a company is on the AIP list, the FDA may suspend its review of all of that company's pending product approval applications. *See* Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy, 56 Fed. Reg. 46191 (September 10, 1991). In addition, the FDA may conduct on-site inspections and review the company's self-audits. Solvay was on the AIP list for six years, from 1997 to 2003. While Solvay could submit new and supplemental drug applications during that time, these applications were not reviewed until Solvay was removed from the list.

74. In 1999, Luvox and Solvay drew fire after the public learned that one of the teenage "Columbine killers" had been taking the drug. In June 2000, Luvox's patent exclusivity expired; sales began a precipitous decline after generics entered the market in November of that year. In 2002, an FDA audit revealed possible inaccuracies in the chemistry, manufacturing and controls section of Solvay's Luvox and Rowasa[4] applications. The FDA notified Solvay and offered it the opportunity to voluntarily withdraw the application for Luvox. In May 2002, Solvay withdrew its Luvox application and suspended sales of Luvox in the United States.[5] The move coincided with the release of expert reports in civil litigation against Solvay for wrongful

[4] Rowasa rectal suppositories are not at issue in this case.
[5] The withdrawal of Solvay's original Luvox application became effective on September 3, 2003.

death stemming from the Columbine killings. By the time Luvox was withdrawn, Medicaid had paid out more than $200 million in claims for Luvox prescribed to its enrollees.

75. In March 2004, as the public was becoming more aware of the danger that anti-depressants can cause mania in children, the FDA requested manufacturers of generic Luvox and other SSRIs to carry stronger warnings recommending close observation of adult and pediatric patients for worsening depression or the emergence of suicidality.

76. In 2006, three years after AIP status was lifted, Solvay made plans to reintroduce a new slightly modified version of Luvox. Solvay collaborated with Elan Pharma International Limited to develop a version of Luvox (Luvox CR) that would supposedly allow the extended release of the drug over a 24-hour period. Solvay and Elan submitted a new drug application for Luvox CR to the FDA in April 2006. In January 2007, Solvay licensed the exclusive rights to the market Luvox and Luvox CR to Jazz Pharmaceuticals. In 2007, after Luvox had been off the market for five and half years, the FDA approved Solvay's new drug application for Luvox's old formulation, allowing Solvay to begin marketing the drug again. Only then did the FDA approve the drug for social anxiety disorder for adults, and until that time, Luvox has never been approved for any indication other than to treat OCD. Solvay obtained FDA approval for Luvox CR to treat OCD and social anxiety disorder in February 2008. Under the Solvay's licensing agreement with Jazz Pharmaceuticals, Jazz Pharmaceuticals paid Solvay $20 million after it received FDA approval for Luvox CR.

b. Off-Label Marketing of Luvox

77. Realizing soon after launch that OCD alone would not provide meaningful sales, Solvay committed itself to promoting off-label uses of Luvox, such as treating depression (despite the weak support for that indication), conditions on what Solvay called the "OC

Spectrum," and anxiety-related disorders. As a result of Solvay's off-label marketing schemes for Luvox, Solvay dramatically increased its sales beyond what it would have achieved through legitimate marketing.

(I) Luvox's Supposed Calming Effect and Promotion for Depression, Anxiety, and Insomnia

Early marketing: OCD as an anxiety disorder

78. In 1994, few people had heard of obsessive compulsive disorder, or "OCD," Luvox's one approved indication. Primary care doctors in particular believed that they rarely encountered patients suffering from "classic" OCD.

79. Physicians were already well-acquainted, however, with SSRIs, the class of drugs to which Luvox belongs. SSRIs Prozac, Paxil, and Zoloft had all received FDA approval for depression by 1994, and Prozac had become the fastest-growing prescription drug in America, with sales over $1.2 billion, while Paxil and Zoloft trailed not far behind. Even after Luvox's depression NDA failed, Solvay counted on riding the coattails of Prozac and other drugs.

80. Yet after two years of promotion, market research indicated that Luvox had failed to differentiate itself from other SSRI's. A 1997 market research study based on psychiatrist interviews demonstrated that most psychiatrists regarded Luvox as a second-, third-, or fourth-line drug therapy. Market research conducted for Solvay by outside consultant TVG in 1999 later revealed that a large majority of primary care doctors were uncomfortable straying from a mental health drug's FDA-approved indication, but few were certain whether Luvox's FDA approval was limited to OCD. Sales figures and market research thus demonstrated that the potential for Luvox prescriptions to arise organically was low; concerted promotional efforts would be needed to change physicians' habits.

81. Initially, in marketing the drug, Solvay's sales aids and suggested screening tools had discussed OCD, but attempted to position OCD more generally as an anxiety disorder. By 1996, Solvay began pressing this anxiety angle further, issuing a screening tool for primary care doctors called the "OC Compendium," which encompassed a list of general questions about anxiety symptoms that would capture virtually any patient suffering from anxiety. Ex. 5 at SOLCID0014916. Solvay's brand management team called this approach Luvox's "anxiety story." *Id.* at SOLCID0014912.

Inflated claims about Luvox's safety record

82. One of TVG's findings in its 1999 marketing research report was that sales representatives' focus should be on safety when introducing Luvox to primary care physicians and that they should point out Luvox's "19 years of worldwide experience in over 12 million patients." But DDMAC, the FDA's regulatory marketing division, had already warned Solvay in 1994 that the almost identical but more modest claim "Worldwide experience in 36 countries and 4.5 million patients" was "misleading" because that experience was gained mostly in treating depression, a use for which the FDA had denied approval, rather than OCD. Ex. 6 at SOLCID0012636. Solvay nevertheless trained sales representatives to make such claims to physicians to boost confidence in the drug and promote use for depression and other off-label uses. *See, e.g.*, Ex. 7 at K00727 ("Used in over 10 million patients worldwide. Over 40,000 patients in clinical trials."). According to Solvay's own consultants, physicians were influenced by such claims, and therefore induced into prescribing Luvox.

Depression, anxiety, and selling Luvox as the "calming" SSRI; claims about FDA approval

83. At an April 1996 training for sales representatives called the "Mental Health MAP II" workshop, representatives learned how to use the OC Compendium. Training materials for MAP II, approved by Solvay's regulatory department, also included the company's script for responding to questions from physicians about Luvox's lack of an indication for depression. The script is riddled with misrepresentations. The materials advise representatives:

- Inform the physician that Solvay Pharmaceuticals is pursuing the depression indication (studies have been completed and an NDA – New Drug Application has been filed with the FDA).

- Also mention, [sic] that Solvay Pharmaceuticals made a practical decision to file first for the OCD indication and then for depression, since the OCD clinical trials were the first to be completed.

- Emphasize that you will keep the physician up-to-date on the status of Luvox Tablets for depression.

Ex. 8 (at SOLCID0015226).

84. MAP II took place over a year after the FDA advised Solvay that its clinical support for a depression indication were inadequate. In truth, while the studies had indeed been completed, *the FDA had already found them to show that Luvox was not effective in treating depression when MAP II took place.* It is true that the OCD studies were completed first; they commenced earlier because it was apparent to Solvay that they had a higher chance of success. Moreover, Solvay omitted mention of the earlier failed NDA for depression. Finally, it is not even clear that Solvay was still pursuing a depression indication by April of 1996.

85. Sales representatives followed Solvay's directive and told physicians that the NDA for depression was pending. Solvay never updated sales representatives further about the

status of the NDA or further studies, and never updated its guidance for handling the inevitable question, even when the company had abandoned its efforts to win FDA approval. Physicians who were wary of prescribing Luvox off-label relied on these assertions in doing so.

86. In 1996 and 1997, Luvox's continued lackluster sales caused the Luvox brand team to redouble efforts to win off-label SSRI market share. Following a national meeting for regional directors in California, Chuck Christophel, Business Director for the Mid-Atlantic region, and Steve Jennings, Luvox Brand Manager, urged John King, then a regional marketing manager in Greensboro, North Carolina, to make a training video on selling Luvox as an SSRI.[6] King enlisted the help of Tom Dovel, a fellow North Carolina regional marketing manager, and the two men filmed the video over the course of a weekend. Solvay representatives met regularly at "Plan of Action" or "POA" meetings organized by brand management teams and the Sales department, and the video was shown at each regional meeting for the 1997 Mid-POA, reaching the entire sales force and numerous executives from headquarters in attendance as "guests."

87. The video warned that "Talking about Luvox for OCD is not going to motivate our physicians to prescribe our drug into the 21st Century." Ex. 9. It instructed sales representatives that: "[Luvox] is not a compound for OCD . . . it is an SSRI and we need to present [Luvox] as an SSRI." It further urged pharmaceutical representatives in these videos to give doctors "good solid information about the drugs at [their] disposal in order to best know how to use them, *indications aside*." King and Dovel were much praised for the video. King received a note of thanks from North Central Regional Sales Director Bruce Birtwell, copying Steve Jennings, Luvox Brand Manager, for King's fine work creating what he called an

[6] The video also addressed selling tactics for Lithobid, a Lithium-based mental health drug not at issue in this case.

"extremely valuable . . . tool." Ex. 10. Birtwell then directed all copies of the video to be returned to him, apparently for destruction.[7]

88. Similarly, District Manager Jeff Osmundson emailed other district and regional managers on April 20, 1999, to describe his best selling tactics: "Avoid OCD in the primary care market. . . . I learned this the hard way. I started out following the OCD theme and got smoked. Nine months later I figured out selling Luvox as a well tolerated SSRI with low sexual dysfunction and a quick washout period worked. When I abandoned my OCD theme market share jumped." Ex. 11.

89. As reflected in the 1997 video, Luvox was known for its sedative "calming" properties. Solvay began to distinguish Luvox from its more successful competitors by telling doctors that Luvox had all of the benefits of Paxil, Zoloft, and Prozac, but with a superior side effect profile, and a "calming effect" appropriate for treating both depression and depression accompanied by anxiety. Training materials were sometimes explicit about the need to promote Luvox for depression. For example, a presentation made to sales representatives in or after 1995 at a regional or national POA meeting introduced Dr. Charles Nemeroff's July 1995 Solvay-sponsored off-label study on Luvox and depression. The presentation recommended a sixty-to-ninety-second script for describing the depression study to physicians, which included among "Questions That Put You In The Sellers Box,"

> "Wouldn't you feel more comfortable using Luvox?" …
> "Isn't it your goal to successfully treat depression?"
> "What if I could show you a drug that works and has no side effects?"

[7] King discovered an overlooked copy in his garage after his termination.

Ex. 12 at 4. Further, an example of a "Smart Question" was "'Based on Dr. Nemeroff's results … [i]n those patients who have depression, would you consider using Luvox?" *Id.* at 3.

90. Such claims were common among Solvay representatives in the field. For example, sales representative Flea Foley's February 24, 2000 call note[8] regarding his visit with Dr. One[9] stated that Foley "[p]ointed out use of luvox as calming agent . . . ." in discussing depression. In a December 14, 1999 call note, sales representative Flea Foley stated that Dr. Two "Use[s] luvox primarily for OCD and some depression with good results. . . . Asked d[octo]r what she uses for anxious depressed p[atien]ts." Ex. 13 at SOLCID0222587. Similarly, a February 29, 2000 call note written by Tracy Rogers noted "find out how Luvox might fit the anxious depressed patient."

91. Luvox's so-called calming effect, though unsupported by clinical trials or studies of any kind, was not just claimed to support use in depression; it was the sole basis for Solvay's off-label promotion of the drug for both stand-alone anxiety and depression accompanied by symptoms of anxiety.

92. Relator John King helped to develop the promotion of Luvox for depression with anxiety disorder at the urging of Solvay management. King discussed promotion for anxiety in two sales training presentations given to sales representatives at a POA meeting in Charleston, South Carolina in March 1998 with Kathleen Milligan, Vice President of Marketing, in

[8] A call note is a record kept by sales representatives following a call on a doctor, describing the call. Call notes are recorded on the same day or within a few days, and, by 2000, were transmitted electronically to a central repository accessible to the representative's supervisor and others.

[9] Prescribers' and other physicians' names have been redacted; concurrently with the filing of this complaint, an index matching pseudonyms used in this complaint with true names will be filed under seal as Exhibit A and served on Defendants.

attendance. Ex. 14 at K00702, K00737. No scientific evidence inspired the claim, and none supported it.

93. At the urging of his supervisor, the Luvox brand team, and top Marketing Department managers, King again incorporated an anxiety promotional message into a July 1999 presentation entitled "Selling Luvox to Primary Care Physicians," which he gave at a POA meeting the next year. The presentation noted that doctors usually use a combination of an SSRI and a benzodiazepine, such as Xanax or Valium, to treat depression-related anxiety. Ex. 7, at K00730. Solvay sales representatives should suggest, the presentation urged, that Luvox alone could achieve the effect of a treatment with an SSRI and a benzodiazepine with just one drug rather than two. Ex. 7, at K00730. Further, the presentation suggested that Luvox was a superior choice for anxiety because it was not addictive like benzodiazepines. Ex. 7, at K00729-K00730.

94. The July 1999 presentation also offered a regimen for switching patients suffering from anxiety from their current SSRI and benzodiazepine to Luvox only; no doctor or scientist was consulted in creating this titration method. Ex. 7, at K00731. Specifically, sales representatives were directed to tell doctors to stop the current SSRI and wait one week before beginning Luvox; after starting Luvox, the doctor could taper the patient's benzodiazepine usage. Ex. 7, at K00731. *Id.* This shift in medication could cause a patient to begin a downward decline into depression and experience higher than usual anxiety after withdrawal from drugs that were known to work and placement on Luvox, a drug that Solvay knew had no proven effectiveness for treating anxiety.

95. Solvay's management showed this July 1999 training presentation at training seminars nationwide and expected sales representatives to use its content to promote Luvox to

primary care physicians. Doctors relied on such information and were induced to prescribe Luvox to patients enrolled in government health programs, among others. King was rewarded for the July 1999 presentation through bonuses and the presentation is discussed as among his achievements in his 1999 annual evaluation.

96. Solvay capitalized on Luvox's supposed calming effect by promoting yet another off-label use: Luvox as a sleep aid. King's July 1999 presentation, adopted and distributed nationwide, urges such promotion, and call notes reflect such discussions with physicians. Ex. 7, at K00731.

(II) OC Spectrum

97. Concurrently, and even before launch, Solvay attempted to expand Luvox sales beyond its narrow indication by promoting to physicians, the FDA, drug compendia, Medicaid agencies, and the medical community at large the concept of the "Obsessive Compulsive Spectrum" ("OC Spectrum"). The OC Spectrum hypothesis rests on the controversial premise that a host of disorders that arguably involve obsessions or compulsions can somehow be considered related and even treated with the same drug regimen. Because Luvox is safe and effective for OCD, the logic goes, it must be safe and effective for a wide *spectrum* of diverse non-approved disorders, such as: attention deficit hyperactivity disorder (ADHD), Asperger's syndrome, autism, antisocial personality disorder, kleptomania, Sydenham's chorea, torticollis, sexual compulsions, schizo-obsessive disorder, basal ganglia disorder, premenstrual dysphoric disorder, depersonalization disorder, epilepsy, anorexia, bulimia, other eating disorders, irritable bowel syndrome, Tourette's syndrome, kleptomania, panic disorder, post-traumatic stress disorder (PTSD), body dysmorphic disorder, hypochondriasis, migraines, compulsive eating,

gambling, social phobias,[10] nervousness, trichotillomania, compulsive buying, hoarding, self-mutilation, and agitation, among others.

98. Solvay's very first sales aids attempted to expand the definition of OCD to other "OC Spectrum" disorders. But upon reviewing those launch materials in 1994, DDMAC warned Solvay that a chart describing disorders that "coexist" with OCD, such as depression, phobia, eating disorder, alcohol abuse, panic and Tourette's was false and/or misleading because it implied that Luvox would be effective in treating OCD patients with these coexistent disorders, when in fact such patients had been ***specifically excluded*** from the studies supporting Luvox's application for an OCD indication. Ex. 6 at 1-2.

99. Solvay nevertheless forged ahead with its OC Spectrum promotion. In late 1995, Kathleen Milligan, Vice President of Marketing, and others approved and finalized a "Distance Learning" program that offered a menu of recorded audio-teleconferences given by mental health researchers and that were eligible for continuing medical education ("CME") credit. The lectures focused on Luvox and OC Spectrum topics, such as "Panic Disorder and the Newer Treatment Options." Representatives would call in to the company's distance learning line during a promotional "lunch n' learn" while visiting a physician. Ex. 15. The lecturers were drawn from Luvox's fiercest advocate "thought and opinion leaders," speakers whom Solvay had in many cases developed over time, as described below in Part VII(B)(iii)(b).

100. A Spring 1996 training video[11] featuring Jack Redmond, Group Product Manager of the Mental Health Marketing Team, circulated to the sales force and senior management, broadcast that Solvay's sales force had already "expand[ed] the definition of OCD through

[10] Over ten years later, the FDA approved Luvox for treating social anxiety disorder in adults.

[11] This videotape was later captured in a transcript forwarded to Kathleen Milligan, Steve Jennings, National Sales Director for Cardiology and Mental Health, Rob Kunis, a product manager, and others. Ex. 16.

discussions of obsessions and compulsions under the broader umbrella of anxiety disorder symptoms," allowing for a new focused product message to capitalize on the market for treatment of patients with symptoms of obsessions and compulsions. Ex. 16 at SOLVACID0012903.

101. John King, then a Regional Marketing Manager in North Carolina, like other managers, gave presentations to sales representatives at regional POA meetings in March 1998. One presentation, which was attended by Kathleen Milligan, Vice President of Marketing for Solvay, reflected Redmond's language describing "expansion of the OCD definition." See Ex. 14 at K00702.

102. King's July 1999 presentation, "Selling Luvox to Primary Care Physicians," given at the July 1999 POA meeting for Solvay's Mental Health sales team, and attended by Steve Jennings, by then promoted from Luvox Brand Manager to Mental Health Group Product Director, and Kathleen Milligan, Vice President of Marketing, discussed the "OC Spectrum" explicitly. Ex. 7 at K00731. In giving the presentation, King used a handout containing diagrams depicting the OC Spectrum, such as one from an article by Harrison Pope, an early proponent of the OC Spectrum concept. Pope had received Solvay grant money to study Luvox and OC Spectrum disorders as early as 1996. Later, Pope received funds on several occasions to study depression and AndroGel, publishing most recently in 2010.[12]

103. Additionally, Solvay Pharmaceuticals hired Medical Education Network to blast-fax a "Medi-fax" on August 1, 1999 to 15,000 psychiatrists. The fax reported on comments made at a Solvay-sponsored symposium on the use of Luvox for pathological gambling, sex

[12] See *infra* at VII(A)(iii)(b)(III).

addiction, impulsivity, PTSD, and bipolar disorders. Luvox product managers Shawn Gearin and Stephen Cornwell then sent an "FYI" to the sales force about it.

104. Luvox's brand managers developed regular "Plans of Action" (POAs) for the drug, including sales goals, incorporated into POA Brand Data Sheets. Some POA Brand Data sheets for Luvox explicitly incorporated specific sales goals in this off-label sector. Indeed, the sales force was expected in some years to grow sales *primarily* through pursuing OC Spectrum prescriptions. For example, the Luvox Psychiatry POA I 2000 Brand Data Sheet stated that the two of the brand objectives were to "Grow obsessions and compulsions market 5%" ***and*** to grow Luvox scripts "in diagnoses related to" OCD from three percent to four percent of market share. Ex. 17 at SOLCID0021200.

105. Especially after 1999, when Solvay assembled a devoted primary care sales team, Solvay's sales force made remarkable inroads with primary care physicians who had less experience than specialists with psychotropic drugs and tended to refer out difficult mental health cases. These doctors were often reluctant to treat "classic" OCD patients suffering from behaviors like checking and compulsive washing of hands, because of the complexity of the disease state and the tenacity of its symptoms. At nationwide trainings and in the field, primary care sales representatives were told to avoid referring to "OCD," which denotes a strange and rare disease state, and to instead use the phrase "OC Spectrum" and discuss "obsessions" and "compulsions" in communicating with physicians. They concentrated on "obsessive and compulsive symptoms" rather than indications. Sales representatives urged physicians to recognize, not "classic" OCD, but milder obsessive and compulsive symptoms, in many of the patients whom they saw daily, such as the hypochondriacs who frequent any primary care

practice. Solvay's sales force was instructed that once defined this loosely, "obsessive and compulsive symptoms" affected as much as ten percent of the general population.

106. Sales representatives' call notes from 1999 and 2000 demonstrate that sales representatives actively marketed the OC Spectrum to physicians. Specifically, in a November 17, 1999 call note, sales representative Mark Kikly stated that he had "[d]iscussed Tourettes syndrom [sic] and ssri's" with Dr. Three, who told him that a patient for whom she had prescribed Luvox for Tourette's had seen no improvement after three weeks. Ex. 13 at SOLCID0222569. Sales representative Flea Foley noted in a March 3, 2000 call note that he and Dr. Four discussed Eric Hollander, a proponent of OC Spectrum and Solvay speaker, and "dr does use LUVOX in OCDS" [OCD Spectrum Disorders]. Ex. 13 at SOLCID0222603. In a May 31, 2000 call note, Foley recorded that he reminded Dr. Five about panic and that Dr. Five said he was using Luvox for autism. Ex. 13 at SOLCID0222615. On June 1, 2000, sales representative Lisa Norton met with Dr. Six, who "[u]ses luvox for patients with trichotillomania." Norton also noted that she "expanded to obsessions and compulsions." *Id.*; *see also* Ex. 13 at SOLCID0222601 (discussion of at least four spectrum disorders; doctor asked to "think of these in terms of obsessional behaviors").

107. Through CMEs, promotional speakers, and their own sales pitches, sales representatives presented Luvox as a one-size-fits-all cure for obsessions and compulsions. The result was an explosion of prescriptions nationwide, few of them on-label.

108. Scant scientific evidence exists to test these non-approved, off-label uses, and some of the research that has been pursued has shown Luvox to be ineffective for such uses. For instance, a double-blind, placebo-controlled study published in 2000 reported that Luvox caused

no improvement in subjects prone to compulsive buying. DRUGDEX's 2008 edition deems research on alcoholism, Asperger's disorder, autism, body dysmorphic disorder, compulsive exhibitionism, compulsive gambling, hypochondriasis, "mixed anxiety and depression disorder," premenstrual dysphoric disorder, repetitive self-excoriation, stereotypy habit disorder, and trichotillomania to be "inconclusive."[13] Tourette's does not even merit a listing in DRUGDEX, despite the existence of research on the subject. In fact, many of the discussions that exist in medical literature regarding the OC Spectrum concept itself have criticized it. Not all disorders involving compulsions, for instance, have a similar source, nor do they necessarily function similarly. Yet physicians prescribed Luvox in reliance on Solvay's misrepresentations about Luvox's effectiveness in treating such disorders. Thus, these "OC Spectrum" uses are not only off-label, but also deceptively promoted and scientifically unsupported.

(III) Downplaying side effects and safety issues

109. The company was well aware of Luvox's problems with SSRI drug interactions and the 3A4 pathway that posed cardiological risks, especially in older populations. Yet Solvay portrayed Luvox as a drug with no significant side effect profile. Representatives promised that the drug was superior to other SSRI's as to sexual side effects and weight gain. In fact, the drug was touted as appropriate for the most fragile populations of patients such as children and the elderly, because of its short half-life, absence of metabolites, and supposed "calming effect." Ex.7 at K00727. Market researchers urged the effectiveness of such claims.

110. Shortly after the FDA approved Luvox, Jack Redmond, Group Product Manager of the Mental Health Marketing Team, and Steve Jennings, Luvox Brand Manager, encouraged

[13] That efficacy rating in the 2008 edition of DRUGDEX signifies that, "Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy."

sales representatives, including John King, to tell doctors that the FDA was not worried about the Cytochrome P450 issue and that if Prozac and other SSRIs were facing the FDA review process now, they too would have the same warnings. King's 1999 presentation on selling Luvox to primary care physicians, approved by the company and distributed to the national sales force, was typical in cautioning sales representatives not to delve into the problems with SSRI drug interactions and the 3A4 pathway, as described above, unless asked by the doctor. The presentation stated, "The bottom line is, SSRI drug interactions do not kill people. Give your doctors this perspective and don't pursue the topic." Ex. 7 at K00728.

111. Luvox's psychotropic profile, meanwhile, posed special problems for children and adolescents. Throughout the years of its promotion, evidence was mounting that taking Luvox and certain other SSRIs increased the risk of mania, including suicidality and homicidal tendencies, particularly in adolescents, as the FDA later cautioned with the first of a series of black box warnings in 2004. Solvay continued to promote Luvox's safety and lack of an agitation side effect in both children and adults, even while its label noted a four percent rate of mania among children versus one percent in adults.

112. One such adolescent prescribed Luvox in the midst of this marketing campaign was seventeen-year-old Eric Harris, who, on April 20, 1999, accompanied Dylan Klebold on a killing spree at Columbine High School. The company's response to the public accusations and physicians' concerns that arose after the Columbine killings was to deny the connection between the FDA's admonitions not to trumpet Luvox's safety profile in children and the mounting evidence of adolescents trying to hurt themselves and others while taking the drug, which Solvay continued to downplay. Doctors were told simply that in Harris's case Luvox had not been used

appropriately. Solvay Pharmaceuticals and Solvay S.A. issued a press release that stated, "There is no evidence to suggest a causal relationship between the prescribed dose of Luvox Tablets and violent or suicidal behavior." Ex. 2.

113. All the while the company knew that episodes of agitation and mania were being reported to the FDA through MedWatch, the FDA's adverse events reporting system. Between November 3, 1997 and October 13, 1999 (the year of the Columbine shooting), the total number of reports related to Luvox was 441 (with a few duplicates). Sixty-five of the reports could be coded into the category of Stimulation. These reactions varied along a continuum from agitation and anxiety to mania. In the category of Depression, Suicide, Self-Injury, and Apathy, thirty-four reports were filed, nine of which overlapped with the stimulant category (twenty-six percent). Under the category Anger, Aggression and Violence, ten cases were reported, five of which overlapped with the stimulant category (fifty percent). The high number of stimulant adverse drug reports and the large overlap of Anger, Aggression, and Violence adverse drug reports with stimulation (fifty percent) support an analysis that Solvay failed to communicate the stimulant-like dangerous effects associated with fluvoxamine. The FDA recognized the danger at last in 2004 and 2006, and placed a black box warning on all SSRIs, including Luvox.

114. Despite knowing that Luvox posed special risks for children, Solvay especially targeted children in promoting Luvox for depression, anxiety, and OC Spectrum disorders. The targeting began at launch, though initially there was no approved pediatric use. Then, in 1997, once the FDA approved Luvox for the treatment of OCD in children and adolescents, Solvay representatives and others began asserting to doctors that since Luvox was safe and effective for children and adolescents with OCD, surely it was safe and effective for "OC Spectrum" diseases

common in children, such as ADHD, anorexia, and body dysmorphic disorder. For example, in a March 3, 2000 call note, Flea Foley stated that when he visited Dr. Seven in Port La Vaca, Texas, he:

> "Talked about OCDS and [doctor] says sees some binge eaters, antisocial personality, whole family with Huntingtons chorea [sic], personality disorders and lots of kids with trichotillomania. Asked d[octo]r to think of these in terms of obsessional behaviors. [Doctor] Said does augment ridlin [sic] with luvox who have ADHD. Will definitely[sic] keep in mind but remind him."

Ex. 13 at SOLCID0222601. On November 15, 1999, Gerald Hellwig recorded in a call note that he "[a]sked" Dr. Eight "to try [Luvox] first line" for "Tourettes kids" [sic] as well as patients in need of a sleep aid. Ex. 13 at SOLCID0222566. In a December 31, 1999 call, sales representative Flea Foley wrote that he reminded Dr. Nine that "Luvox was safe and effective in children and the first to be indicated for OCD in children, and although he doesn't[sic] see children, if it is safe and effective in your most fragile p[atien]ts, why wouldn't you use it for your elderly p[atien]ts. Dr agreed." Ex. 13 at SOLCID0222589. As a final example, on July 26, 2000, Holly Deprete noted that she had discussed with Dr. Ten off-label studies "regarding "Tourettes [sic] and Tics," and planned on her next visit to "discuss the Luvox benefits in children." Ex. 13 at SOLCID0222625.

115. Moreover, Solvay's sales force actively targeted both pediatricians and pediatric psychiatrists, urging the use of Luvox to treat not only pediatric OCD, but also pediatric depression, anxiety, and depression with accompanying symptoms of anxiety. Those overtures are captured in the call notes recorded by sales representatives following physician calls, as well as in performance evaluations, emails within sales districts, and other materials. Management

and representatives recruited speakers to promote these messages as well, through live and recorded promotional and CME lectures of every kind.

116. In promoting Luvox's supposed ideal side effect profile for children, the elderly, and other fragile populations, the company deliberately omitted and downplayed life-endangering side effects. Physicians prescribed Luvox in reliance on these assurances.

c. Luvox in DRUGDEX

117. DRUGDEX does not support the off-label uses that Solvay promoted. Some promoted uses have never been listed in DRUGDEX. Others lost legitimacy when DRUGDEX delisted or downgraded them by 2008. One use, depression was one that DRUGDEX could never bolster after the FDA twice rejected it. Still others listed such poor evidence of efficacy that it cannot be deemed support. Others still, though listed, were categorized by DRUGDEX as ineffective. Finally, some are supported only or mainly by manufactured studies that were either sponsored by Solvay, or researched by Solvay beneficiaries.

118. Among the uses promoted by Solvay that have never appeared in DRUGDEX are use as a sleep aid, all children's prescriptions outside of OCD, and the following OC Spectrum disorders: stand alone anxiety disorder, Tourette's syndrome, anti-social personality disorder, schizo-obsessive disorder, sexual compulsions, and ADHD. Hypochondriasis appeared only after 2003, by which time Solvay had pulled Luvox from the market.

119. In 1996, only nine off-label uses were listed in DRUGDEX for Luvox; the pertinent uses include compulsive exhibitionism, depression, eating disorders, headache, and panic attacks. Sometime between 1996 and 2003, DRUGDEX's Luvox entry exploded to twenty-seven uses, including adding Asperger's disorder, autistic disorder, body dysmorphic

disorder, compulsive buying, depression with anxiety disorder, irritable bowel syndrome, kleptomania, pathological gambling, posttraumatic stress disorder, premenstrual dysphoric disorder, stereotypic behavior, and trichotillomania. Just as abruptly, by 2008 DRUGDEX had completely delisted headaches/migraines, kleptomania, and irritable bowel syndrome, apparently because of concerns about the listings.[14] That edition also deemed most of the OC Spectrum uses "inconclusive," including listings for PTSD, autism, body dysmorphic disorder, and eating disorders, all downgraded from 2003 ratings of "effective" or "possibly effective" with fair or good documentation. Yet the authorities cited for each of these listings changed little. The delisting and downgrading demonstrate that the uses had never been substantiated by reliable evidence.

120. Compulsive buying has been listed since at least 2003, based on a double-blind, placebo-controlled study of thirty-seven subjects, but the study's conclusion was that Luvox offered no improvement and was not recommended. Other listings cite only a case study or a few subjects. Asperger's syndrome, for instance, cites anecdotal evidence about one eight-year-old boy. Compulsive exhibitionism is supported by one thirty-six year old man's experience. Hypokinetic rigid syndrome, kleptomania, and irritable bowel syndrome also relied on single case studies. A number of others, such as compulsive gambling, cite studies with ten or fewer subjects. Few of the studies are double-blind with placebo controls.

121. While depression was listed in DRUGDEX from at least 1996, and depression accompanied by anxiety was first listed sometime between 1996 and 2003, somewhere between

[14] DRUGDEX offers this policy for why a listing may be removed: "[h]istorical information in our databases is subject to revision or removal if it becomes outdated based on new developments or lack of substantiation by methodologically sound clinical trials." The lack of substantiation by clinical trials is obviously not an initial bar to inclusion; apparently at some point years later this is potentially deemed a problem.

2003 and 2008, DRUGDEX's authors, though listing the same research, downgraded depression from its most supportive category into a middle range, with the strength of the recommendation now limited to "in some cases." Moreover, the FDA has specifically rejected the new drug application submitted for depression twice; given the FDA's position, DRUGDEX's listing of depression, however much supposed support it contains, cannot render it a "medically accepted indication."

122. Further, while the studies cited in DRUGDEX in connection with off-label uses for Luvox are varied in terms of sponsorship, the studies cited under OC Spectrum uses were disproportionately sponsored by Solvay or Solvay-owned subsidiaries, or authored by Solvay national speakers, though this relationship is omitted from DRUGDEX and often from the studies themselves. For instance, trichotillomania, compulsive gambling, premenstrual dysphoric disorder, irritable bowel syndrome, hypochondriasis, autistic disorder, body dysmorphic disorder, and compulsive exhibitionism were all supported only by studies involving such conflicts of interest.

d. Examples of False Luvox Claims

123. Solvay's off-label marketing campaigns paid off in Luvox sales. While Luvox never became as well-known as Prozac to the public at large, it was a top-selling drug for Solvay for years, with at least $6 million dollars in Medicaid claims in the state of Texas alone. The majority of Luvox's Medicaid sales were for indications other than for OCD.

124. A review of the Texas claims data and call notes written by Solvay sales representatives about their sales calls on doctors regarding Luvox demonstrates that doctors

received off-label pitches and then prescribed Luvox for off-label uses. The chart below is a representative sample of this data:[15]

Physician Name City/State	Off-label Message and Date Received	Medicaid Patient Control Number (Redacted)	Diagnosis	Diagnosis Date	Medicaid Rx Fill Date
Dr. Two San Antonio, TX	12/14/1999 Sales rep call note documenting anxiety and depression pitches	50982**** 50613**** 51305****	Severe Recurrent Psychotic Depression Manic Depression Severe Recurrent Psychotic Depression	7/26/2000 10/25/2000 4/1/2001 6/4/2001	8/7/2000 10/23/2000 12/2/2000 5/30/2001 4/4/2001 6/5/2001 7/2/2001
Dr. Three Corpus Christi, TX	3/7/2000 Sales rep call note documenting "calming SSRI" and OC Spectrum pitches	50939**** 51154****	Attention Deficit with Hyperactivity Attention Deficit with Hyperactivity	3/31/2000 1/8/2003 2/18/2003	4/16/2000 5/13/2000 1/15/2003 2/19/2003

125. A more complete summary chart of representative examples of Luvox off-label prescriptions is attached as Exhibit 18.

ii. Aceon (Perindopril)

a. Regulatory History

126. In December 1993, the FDA approved Aceon (Perindopril) only for the medical indication of "essential hypertension," or high blood pressure. *See* Aceon label, *available at* http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020184s011lbl.pdf. In May 1999, Solvay acquired the rights from Servier S.A., a French pharmaceutical company, to market

[15] In order to protect patient confidentiality, Relators refer to patients by a partially redacted patient control number.

Aceon in the United States. When Aceon entered the market, it was the 11th "ACE" inhibitor[16] to arrive. The market's response to its launch was a collective sigh of indifference. Until 2005, "essential hypertension" was the drug's only approved indication. In August of 2005, the FDA approved the drug for treatment of patients with stable coronary artery disease to reduce the risk of cardiovascular death or myocardial infarction. Aceon has not received approval for any other indications.

b. Off-Label Marketing of Aceon

127. Even before the launch of Aceon in October 1999, Solvay promoted Aceon for off-label uses. Off-label promotional schemes used to sell Aceon included the concept of "Arterial Wall Compliance," the "diabetic kidney" campaign, and the "PROGRESS" prevention-of-secondary-stroke campaign. Each of the schemes is discussed in detail below.

(I) Arterial Wall Compliance

128. As part of Solvay's 1999 launch of Aceon, Solvay promoted Aceon for "arterial wall compliance." Solvay stressed to doctors that Aceon delivered a structural change in all arteries by remodeling them, whereas other hypertension drugs merely lowered blood pressure. In doing so, Solvay pointed to animal research cited on Aceon's label that suggested such a potential effect.

129. Solvay falsely marketed the arterial wall compliance concept even though it knew that the claims were well beyond the bounds of the limited purpose for which the FDA had approved Aceon and lacked any scientific justification. The FDA explicitly challenged Solvay

[16] ACE inhibitors lower blood pressure by inhibiting the activity of angiotensin converting enzyme ("ACE"), which converts angiotensin I to angiotensin II. Angiotensin II causes the muscles surrounding blood to contract, narrowing the blood vessels and increasing the pressure within the vessels. By inhibiting ACE and thereby decreasing the production of angiotensin, the blood vessels dilate and blood pressure is lowered.

on its promotion of unfounded arterial wall compliance effects. Indeed, in July of 1999, even before launch, DDMAC, having reviewed proposed launch sales materials, prohibited Solvay from claiming Aceon's superiority to competitors on the basis of arterial wall compliance, noting that such claims are unsupported by Aceon's label:

> DDMAC would consider your presentation of claims and representations related to arterial compliance to be misleading. First, the effect of antihypertensive agents, including Aceon, on arterial compliance has not been conclusively demonstrated in clinical trials. Second, the clinical significance of an effect of arterial compliance has not been established. Third, the effect of Aceon on arterial wall compliance, demonstrated in animal models, may not be applicable to humans. Therefore, your presentations concerning the arterial compliance of Aceon would be misleading because they are not based on substantial evidence.

Ex. 19 at SOLCID0157877-78.

130. Solvay's training materials confirm that Solvay knew that its arterial wall compliance claim was not only off-label, but without proof. When James Maxson, a Regional Account Manager, emailed other managers tips on what ICD-9 codes would ensure coverage for Aceon in February 2002, he acknowledged that vascular compliance claims were off-label, noting, "Even though we do not have an indication for Arterial Wall Compliance …" Ex. 20. In training its sales force on selling claims of arterial wall compliance, Solvay admitted to its sales force that: "We don't have proof yet. We cannot put an outcome paper in front of [physicians]."

131. Yet arterial wall compliance was initially Solvay's only potential basis for distinguishing itself from other ACE inhibitors. The company dubbed Aceon "the arterial Ace" and a "tissue Ace" on this basis. Arterial wall compliance appeared in virtually every sales aid and promotional piece Solvay produced for years. For example, the nationally disseminated sales aid entitled "Continuous threat: Hypertension Never Sleeps" displayed vascular diagrams

and described a theory of vascular compliance as well as a description of very limited clinical studies under the heading, "24-Hour Aceon – Proven Vascular Benefits."

132. So despite this lack of proof and the FDA's admonitions, Solvay mandated that its representatives push the Arterial Wall Compliance message to doctors ever more vigorously. In addition, representatives throughout the United States paid specialists to deliver Solvay's Arterial Wall Compliance message to primary care doctors, often using Solvay's own materials.

(II) 24-hour Control for the "Diabetic Kidney" and the "Aceon Refinement Message"

133. In February of 1999, several months before launch, Collegeville Advertising Associates ("CAA") reported to Doug Haling, Aceon's brand manager, on focus groups it had conducted with primary care physicians to test Aceon's positioning. It concluded that what Solvay called the "24-hour control" story, perhaps in tandem with the arterial wall compliance story, tested best. It further recommended exploring the 24-hour control story in particular with "renally-impaired patients," *i.e.* diabetics. That guidance from Solvay's marketing experts would shape Aceon's "brand strategy," including research decisions, for years to come.

134. With regard to a launch price, CAA recommended relatively high pricing on the basis of Aceon's 24-hour control claims, with prices just under Altace and Monopril, which were other brands positioned as "24 hour ACEIs," and promoting Aceon "as having superior benefits to these brands at lower cost." In April of 1999, a group of managed care advisors paid by Solvay to attend a "Cardiovascular Managed Care Advisory Board" meeting at the luxurious Broadmoor Resort in Colorado Springs expressed reservations about Aceon's relatively high pricing and doubts about Aceon's competitive claims, including the 24-hour control claim. Ex. 21 at K2117-19.

135. Solvay's 24-hour control claim was that Aceon provided "complete 24-hour protection of blood pressure," allowing for the complete protection of a patient's kidneys. Most blood pressure medicines slowly wear off, allowing a rise in blood pressure during the last four to six hours of the dosing interval. This elevated blood pressure is theoretically problematic for a patient's kidney because a substantial increase in blood pressure could prevent the kidney from properly functioning, in turn allowing protein to spill into the urine. Solvay led doctors to believe that Aceon provided patients with better blood pressure control than competitors throughout the dosing interval because, it claimed, Aceon did not allow a spike in blood pressure during the last four to six hours of the dosing interval; accordingly, Aceon allegedly prevented protein from spilling into the urine.

136. Encouraged by its advertising consultant, Solvay asked sales representatives to focus use of this "24-hour control" story on doctors' diabetic patients. Diabetes can damage the kidney's system of filtration, causing protein to pass through the kidney and into the urine. Over time, this damage can lead to kidney failure. Hypertension is a particular concern in diabetic patients because damaged kidneys cannot handle high blood pressure and fail more quickly than healthy kidneys.

137. While hypertension is a special concern for diabetics, no scientific support exists for Solvay's diabetic kidney claims. Although one early study showed that Aceon provided 24-hour protection, other studies have provided conflicting data, demonstrating that Aceon did not provide 24-hour protection as marketed. Moreover, Solvay asked physicians to assume that in the four to six hours before a diabetic patient takes his or her daily ACE inhibitor manufactured by any of Solvay's competitors, the patient's blood pressure not only rises, but rises substantially

enough to risk the spillage of protein into urine. That leap in logic is dubious at best; the FDA has already determined for each competitor drug that a single daily dose is safe and effective and more frequent dosing is unnecessary.

138. The 24-hour control story, including the targeting of diabetics, and the arterial wall compliance story were two of a handful of sales approaches taught to sales representatives initially to sell Aceon. Despite these promotions, a market research report issued in April 2000 noted that the reason for the research is that "prescription volume has been lower than anticipated." In fact, the doctors who were studied told researchers that they had little or no reason to prescribe Aceon, and those who prescribed it did so for reasons like, "I have some samples lying around," or to "do the rep a favor." Sales were flat after Aceon's first twelve months on the market. Sales were increasing in John King's sales territory, however, and in October of 2000 he was asked to assist in retooling Aceon's message.

139. Solvay embarked on a campaign to increase its Aceon profits by focusing virtually all promotion on the sixteen million Americans nationwide that have diabetes—a highly visible patient population for Solvay's doctors—and repackaging the deceptive concept of the diabetic kidney into a terse script for sales representatives to use. The result was the "Aceon Refinement Message," described in a PowerPoint presentation that was tested successfully with market research in early November 2000 and rolled out to the entire primary care sales force in November and December 2000 through teleconference sessions with district managers. Ex. 22 (Aceon Refinement Message); Ex. 23 (rollout schedule); Ex. 24 (message refinement strategy).

140. Solvay adopted the "Aceon Refinement Message" as the single sales campaign to be used nationwide to promote Aceon. Solvay's management demanded that its representatives

"aggressively sell[] this message." In November 2000, John Hepfer, Director of Cardiovascular Medical Education, prepared a presentation on diabetes medical background to be given to sales representatives, in an attempt to retroactively provide clinical backing for the message.

141. Solvay's top executives, including Ed Schutter, Solvay's National Sales Director of Primary Care Sales Force, and John Hepfer, Solvay's Cardiovascular Marketing Department, and King's immediate supervisors endorsed this campaign. King received a certificate of Achievement for his work. Ex. 25.

142. Following the national roll-out of the Aceon Refinement Message in January 2001, Michael Bullington, Regional Business Director for the Central Region, forwarded by email to district managers, Steve Jennings, then Business Director, Cardiovascular and Mental Health Marketing, Tom Schenker, National Sales Director for Primary Care, and Jim Hynd, Vice President of Marketing, an "Aceon Sales Tip" from John King, and announced that it would be one of a continuing series. The email stressed to King's representatives that "physicians need to prescribe Aceon for a reason . . . other than you. **This reason is the diabetic kidney.**" Ex. 90 (emphasis in original). It advised that a representative still had work to do if that representative's physicians did not immediately answer "my diabetic kidneys" as the reason they prescribed Aceon. *Id.*

143. Senior management incorporated the message into a key strategy in the March 2001 Business Plan for Aceon. "Refine current training materials and develop new programs that educate representatives on ACE inhibitors, disease states (diabetes, stroke) and competition." Ex. 26 at SOLCID0049270. The message was incorporated into 2001 district business plans in several states and regions, such Georgia, Illinois, Louisiana, Tennessee, Texas

and Arizona. District Manager Dan Gobat's Atlanta, Georgia District Business Plan included diabetic kidney audio-conferences, speaker events, and professional services events with physician groups, all on the diabetic kidney. Ex. 27 at KD00556-57). Andre L. Sconiers' Chicago District plan lists "Target diabetic market" as an opportunity. Jim Potter's Nashville District business plan lists as a specific district strategy "Continue to deliver the Diabetic Kidney Presentation." The New Orleans District business plan states that the main targets for selling Aceon will be primary care doctors, because they are most "easily influenced" and manage "all but the most acute diabetic patients." Ex. 28 at K00384. Tom Gumbel, District Manager in Indianapolis, listed "Aceon 24 hr. control key in diabetics" under "Critical Success Factors," in his 2001 district business plan. Cassandra Perkins, District Manager in Phoenix, forwarded Doug Haling's call-in information for IRA audioconferences on the diabetic kidney to her team in Arizona and Texas in April 2001. Sales representatives and others received these directives and promoted the message in the field. A November 2000 e-mail from Lisa Cooper, District Manager for Cleveland, to John King and Tom Dovel let them know that she had personally tried the Aceon refinement message and experienced its instant success. Ex.29.

144. Coachable speakers, were recruited to spread the diabetic kidney message, including Dr. Gerald Kumin and Dr. Michael Broder, examples of whose lectures are described in Part VII(B)(iii)(b) below.

145. By June 2001, Solvay had received market research that physicians ranked Aceon first among anti-hypertensives in effectiveness in diabetic patients and in 24-hour control. John Hepfer, Director of Cardiovascular Medical Education, reported to King:

> I think the help you gave us with the 24hr Diabetic message paid off. Aceon did pretty good. Comparisons were against both ACE's and ARB's [types of anti-hypertensives]. This is what the physicians reported:
>
> - Effective in Diabetic Patients – ACEON finished first. …"

Ex. 30.

146. The Aceon Refinement Message dramatically boosted sales of Aceon from approximately $4.5 million in 2000 to over $21 million in 2001, and King was lauded as a hero. Solvay had succeeded in creating a brand for Aceon as a diabetic kidney treatment.

(III) Stroke Prevention/PROGRESS Trial

147. In the meantime, Solvay had sponsored extensive research in the hopes of proving Aceon's effectiveness in preventing secondary stroke. A comprehensive public relations strategy was in place by October of 2000, including recruiting physicians to attend the June 2001 unveiling in Milan, Italy. Before the PROGRESS trials were completed, Solvay commissioned an expensive econometric study to learn the trial's likely effect on Aceon sales. The report, issued in October 2001, reflects analysis of over 5,300 physician questionnaires across relevant specialties. It forecasted significant increases in Aceon prescriptions over five years attributable to various potential PROGRESS outcomes.

148. But the "PROGRESS" trial results that were issued from Milan and published in *Lancet* in September 2001 were disappointing; they showed that the incidence of secondary strokes in study subjects was lowered, but only once a rarely used diuretic, indapamide, was added to Aceon. Ex. 32 (*Lancet* article on PROGRESS trial). There was no indication that Aceon added any synergistic effect to the diuretic. Plans to file for the required additional indication with the FDA were apparently tabled. Solvay executives considered how to react. They convened their previously-planned U.S. Advisory Board on PROGRESS on June 19, 2001,

including CEO Harold Schlevin, John Hepfer, Doug Haling, Lowell Scott, and Steve Wojtanowski, to discuss PROGRESS results and "[g]ain an insight as to how to position the PROGRESS data …"

149. Their next moves were more cynical. Aceon's brand team and Solvay's highest echelons of executives determined that PROGRESS was a failure and that Aceon could not be distinguished in any meaningful way from other ACE inhibitors; accordingly, they adjusted their long term sales goals dramatically downward, as Bob Solheim, Steve Jennings and Alan Ryan explained years later in a 2003 memorandum to the Aceon file. Ex. 31. *But the message they decided to provide to the sales force was that PROGRESS was a breakthrough for the drug and must be rigorously promoted.*

150. The company adopted the slogan, "Progress to 24-hour control" with a wink and a nod, hoping that the FDA would not catch the off-label reference. Its 2002 positioning statement became: "Aceon is the only true 24 hour BP control ACEI, with a 97-100 percent trough-to-peak ratio, making it ideal for stroke and diabetic patients." Ex. 33 at KD00072.

151. Aceon's 2002 Business Plan included comprehensive plans to train speakers on PROGRESS and use the study to improve formulary positioning nationwide. Solvay required its sales force to play audio-CMEs about the PROGRESS trials in doctor's offices and other promotional settings, despite the CMEs' off-label content. In fact, as part of Solvay's business strategy, Jim Prasch, National Sales Director, Primary Care, mandated that sales representatives hold two PROGRESS CD CMEs per week, or twenty to fifty CMEs per quarter, in clear violation of the OIG guidance against manufacturers' promotion of drugs through CMEs. Solvay partnered also with the National Stroke Association in 2002 to produce a similar CME

under Solvay's influence, but with a veneer of independence; Shawn Durrani, Associate Product Manager for Aceon, directed sales representatives to distribute brochure invitations to the off-label CME to their target physicians.

152. Live speakers also made an impact. Between February and August of 2001, one sales representative alone, Tonya Stringer, coordinated ten PROGRESS speaker events, delivering its message to at least thirty-six physicians. Ex. 34. In February 2002, 120 physicians met at a single event in Charleston, West Virginia, organized by sales representatives, to hear Dr. Dr. Ninety-one discuss PROGRESS and the role of Aceon. Dr. Richard Aguilar gave thirty-nine talks in 2002, all concerning the PROGRESS trial.

153. Despite PROGRESS's disappointing results, the push to promote PROGRESS spurred a number of Solvay's more dubious marketing endeavors. Southwest Regional Business Director Christa Townsend directed a district manager to audio-record a teleconference with Aceon advocate Dr. Richard Aguilar regarding PROGRESS. She distributed ninety copies of the tape throughout her region before, at Jim Prasch's direction, ordering the tapes to be destroyed because of their off-label content. Jennifer Ross, a sales representative under district manager Kevin Maher, who reported in turn to Christa Townsend, worked with a neurologist in her Austin, Texas territory to produce a letter that he sent to his patients about the risk of stroke and how PROGRESS had demonstrated that Aceon more effectively managed that risk; on a teleconference, Townsend urged district managers to do the same in their districts, and they followed that direction. Solvay's upper management and Aceon marketing team were well-aware of the tactics employed and approved in regions like Townsend's, but, because such regions were meeting and exceeding sales goals, their tactics and conduct were not challenged.

154. Indeed, by November 2001, while Aceon failed as a blockbuster drug, the impact of the diabetic kidney and secondary stroke campaigns was profound: Aceon had the fastest growing market share out of nine approved ACE inhibitors with 142.6 percent growth. By July 2002, Aceon had reached 89.71 percent of its annual sales goal.

(IV) *Consequences of off-label campaigns*

155. Solvay's lies likely resulted in inadequate and inappropriate care. Unsuspecting doctors believed Solvay's misleading representations that Aceon was a better hypertension drug than its competitors because it offered complete 24-hour protection of blood pressure, treated the diabetic kidney, helped remodel arteries through arterial wall compliance, and prevented secondary stroke. Consequently, these doctors prescribed Aceon instead of other, often less expensive drugs. But Aceon did not provide extra protection to the diabetic kidney, nor did it prevent secondary stroke or uniquely address arterial wall compliance.

c. Aceon in DRUGDEX

156. The 2003 edition of DRUGDEX and its listings arguably related to diabetic kidney and secondary stroke hardly inspire confidence in these uses. That edition contains an entry for "hypertension – diabetes," that cites various research from the early 1990's, most of which is Solvay-supported, concluding that Aceon can effectively treat hypertension in diabetics. One sentence suggests that Aceon may have special properties beneficial to diabetics that other ACE inhibitors lack, but the citation listed is "(Anon. 1991)." A second entry exists for "nephropathy – diabetic," which concerns claims of special protections for the diabetic kidney. But none of the research cited involved Aceon; the claims are made about the entire class of ACE inhibitors. As for prevention of secondary stroke, research cited in support consists of the

same, unsupportive PROGRESS study that Solvay promoted beginning in 2001, plus one additional 1996 sponsored study mentioned as the rationale for choosing Aceon for PROGRESS. Sometime between 2003 and 2008, DRUGDEX's authors, though listing the same research, downgraded listings for both hypertension in diabetics and stroke from most supportive category into a middle range, with the strength of the recommendation now only "in some cases." "Nephropathy – diabetic," addressing the heart of diabetic kidney assertions, was eliminated completely. "Arterial wall compliance" is not listed in DRUGDEX. Even if the listing of atherosclerosis (hardening of the arteries) were understood to cover this use, the 2003 listing seemed this treatment "ineffective," and the 2008 edition omitted it. Thus, the only listings covering the off-label uses at issue with this drug do not support those uses.

d. Examples of False Aceon Claims

157. A review of Texas claims data provides some representative examples of Texas doctors receiving off-label pitches, resulting in Aceon prescriptions.

(I) Arterial Wall Compliance

158. Representative examples from the Texas claims data demonstrate that several physicians wrote Aceon prescriptions after attending talks about arterial wall compliance. For example, Drs. Eleven, Twelve, Thirteen, and Fourteen attended a talk given by Dr. Ninety-two on arterial wall compliance and the diabetic kidney on November 23, 1999. *See* Ex. 35 at SOLCID0108077. None of these doctors had prescribed Aceon before attending this talk. After attending this off-label program, all of these doctors prescribed Aceon to Medicaid patients:

Physician Name	Number of Filled Aceon Medicaid Rx from October 1999 to October 2004
Dr. Eleven	123
Dr. Twelve	44
Dr. Thirteen	22
Dr. Fourteen	23

159. More complete summary charts of characteristic example prescriptions by each doctor are attached in Exhibit 36.

160. In February 2000, Solvay paid Dr. Fifteen $250.00 to attend a Solvay Cities presentation, in which he provided feedback to Solvay sales representatives hoping to strengthen their sales pitches. Ex. 38 at SOLCID0011001. Among the pitches he heard that day was Solvay's claims surrounding arterial wall compliance. Ex. 127 at KD00696. In September 2000, Dr. Fifteen attended a Speakers Training program held in Boston; the program focused on arterial wall compliance. Ex. 37 at SOLCID0093082, SOLCID0093088. He also received $2,000.00 that month for participating in a "ride-along," during which he traveled with Solvay sales representatives as they called on doctors and pitched Aceon for off-label uses. Ex. 38 at SOLCID0066980. On June 19, 2001, Solvay paid for Dr. Fifteen to fly to Milan, Italy for the unveiling of the PROGRESS results. *Id*. at SOLCID0047089-90. Solvay then paid Dr. Fifteen for giving presentations on the PROGRESS results in an attempt to influence his peers. *Id*. Before participating in that first Solvay Cities event, Dr. Fifteen had never written any Medicaid prescriptions for Aceon. From February 1, 2000 to June 21, 2005, Dr. Fifteen wrote 365 Medicaid prescriptions for Aceon. Ex. 38. Later, Solvay began targeting Dr. Fifteen for AndroGel and he soon became a prescriber. Dr. Fifteen's prescribing history provides a good example of how Solvay's off-label marketing and kickbacks schemes went hand-in-hand to induce high-Medicaid prescribing-physicians to prescribe and continue prescribing Solvay drugs.

(II) Diabetic Kidney

161. A review of the Texas claims data also shows that the diabetic kidney campaign was effective. A representative sample of this data showing two of the scripts that resulted from this campaign is set forth below:

Patient Control Number (Redacted)	Diagnosis	Diagnosis Date	Medicaid Prescription Fill Date
10012****	Diabetes Mellitus Type II	4/4/2002	5/25/2002
10012***	Diabetes Mellitus Type II	4/4/2002	6/22/2002
10601****	Diabetes Mellitus Type II	11/15/1999	11/16/1999
10601****	Diabetes Mellitus Type II	11/15/1999	12/6/1999
10601****	Diabetes Mellitus Type II	11/15/1999	1/10/2000

162. A more complete summary chart of representative examples of Aceon prescriptions for diabetic patients is attached in Exhibit 36a.

(III) PROGRESS

163. On July 12, 2001, Dr. Sixteen attended a program on the PROGRESS study that discussed the off-label use of Aceon as a stroke preventative. From March 2001 until February 2002, Dr. Sixteen wrote five Aceon prescriptions, one of which was for a Medicaid patient. *Id*. From July 16, 2002 until March 9, 2004, Dr. Sixteen wrote twelve more Aceon Medicaid prescriptions. *Id*.

164. A representative sample of the Texas claims data demonstrates that other physicians also prescribed Aceon for stroke-related diagnoses after the PROGRESS campaign rolled out.

Patient Control Number (Redacted)	Diagnosis	Diagnosis Date	Medicaid Prescription Fill Date
50643****	Cerebrovascular Disease Unspecified	6/8/2004	8/3/2004
50643****	Cerebrovascular Disease Unspecified	6/8/2004	9/20/2004
50643****	Cerebrovascular Disease Unspecified	6/8/2004	11/8/2004
50643****	Cerebrovascular Disease Unspecified	6/8/2004	1/7/2005
51473****	Acute, but ill-defined, Cerebrovascular Disease	8/5/2002	8/5/2002
41308****	Acute, but ill-defined, Cerebrovascular Disease	5/25/2001	6/29/2001
41308****	Acute, but ill-defined, Cerebrovascular Disease	5/25/2001	7/30/2001
41308****	Acute, but ill-defined, Cerebrovascular Disease	5/25/2001	9/12/2001
41308****	Acute, but ill-defined, Cerebrovascular Disease	5/25/2001	10/29/2001
41308****	Acute, but ill-defined, Cerebrovascular Disease	5/25/2001	12/17/2001

165. A more complete summary chart of representative examples of Aceon prescriptions for stroke patients is attached in Exhibit 36b.

iii. AndroGel (testosterone gel)

a. Regulatory history

166. In 1995, Unimed Pharmaceuticals acquired exclusive rights for Laboratoires Besins Iscovesco S.A. to market AndroGel in the United States. Unimed Pharmaceuticals then sponsored an application for orphan drug designation, which was approved in February 1996, for AndroGel in the treatment of weight loss in AIDS patients with HIV-associated wasting. The

FDA has never approved AndroGel to treat weight loss in AIDS patients with HIV-associated wasting. At the same time, Unimed conducted clinical trials for the treatment of testosterone deficiency. In April 1999, Unimed Pharmaceuticals, Inc. submitted a new drug application for AndroGel. Shortly afterward, in July 1999, Solvay acquired Unimed and the rights to AndroGel.

167. In 2000, Solvay obtained FDA approval for AndroGel (testosterone gel) for particular types of male hypogonadism defined as follows:

> AndroGel is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone:
>
> 1. Primary hypogonadism (congenital or acquired) – testicular failure due to cryptorchism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. …
> 2. Hypogonadotropic hypogonadism (congenital or acquired) – idiopathic gonadotropin or …LHRH … deficiency or pituitary-hypothalamic injury from tumor, trauma, or radiation.

Ex. 39 (original AndroGel label).

168. Hypogonadism as defined on the FDA-approved label and as understood in the medical community is a rare condition occurring in men across all age groups associated with a deficiency or absence of endogenous testosterone. The diagnosis of hypogonadism in adult males involves a comprehensive history and physical examination in addition to laboratory test for levels of testosterone and gonadotropins, and possible further testing to determine the cause. The central study featured within AndroGel's label, which is approved by the FDA, used a simple blood test, best administered in the morning, and called a "total testosterone" test. Subjects in the study whose tests reflected total testosterone levels of 298 to 1043 ng/dl (nanograms per deciliter) were considered to have normal testosterone levels; blood levels lower than 298 ng/dl were considered hypogonadal.

169. Common causes of primary hypogonadism include Klinefelter's syndrome, a genetic abnormality in which a male has two or more X chromosomes in addition to one Y chromosome causing abnormal development of the testicles, anorchia, the absence of testicles at birth, or an injury to the testicles. Secondary hypogonadism can occur due to a problem with or injury to the pituitary gland or hypothalamus. The hypothalamus normally produces gonadotropin-releasing hormone, which signals the pituitary gland to make luteinizing hormone. Luteinizing hormone signals the testes to produce testosterone. Some common conditions that can cause secondary hypogonadism include Kallmann's syndrome (abnormal development of the hypothalamus, which affects the testosterone production cycle) and pituitary tumor.

170. In June 2001, Solvay/Unimed joined forces with TAP Pharmaceutical Products, Inc. to co-promote AndroGel in the United States; the agreement ended in 2003.

171. AndroGel is a gel containing synthetic testosterone. The gel is applied to the shoulder, upper arms, and/or the abdomen once daily so that the testosterone can be absorbed through the skin. The product originally came in individual packets. Solvay launched new packaging for AndroGel on September 8, 2004 in the form of a mitered pump.

172. In June 2007, Solvay announced that it had submitted a new drug application for AndroGel for treatment of Constitutional Delay in Growth and Puberty in male adolescents ages 13 to 17 years old. The FDA has still not approved this use.

173. In May 2009, after receiving reports of adverse effects in children who were inadvertently exposed to testosterone through contact with a person being treated with testosterone products, the FDA required Solvay and its competitor to include black box warnings on their products, AndroGel and Testim. *See* Press Release, FDA, Testosterone Gel Safety

Concerns Prompt FDA to Require Label Changes, Medication Guide" (August 26, 2009), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149580.htm. Although the labels for both products warned users to wash hands after application of the product and to cover the treated area with clothing and warned of the potential risk of transfer to female partners, neither label mentioned any risk of transfer to children.

174. Signs and symptoms in the exposed children included inappropriate enlargement of the genitalia, premature development of pubic hair, advanced bone age, increased libido, and aggressive behavior. *Id*. In addition, some of the children had to undergo invasive diagnostic procedures. *Id*. In most cases, these adverse events regressed once the child was no longer exposed to the testosterone products. In a few cases, the adverse effects experienced by the children did not regress; for example, some children's enlarged genitalia failed to return to age-appropriate size and/or their bone age remained higher than the children's chronological age.

b. Off-Label Marketing of AndroGel

175. Similar to Luvox, AndroGel was approved for use in a small population of patients—men with hypogonadism. According to many experts, including those cited in a 2002 *New Yorker* article,[17] hypogonadism affects tens of thousands of American men—hardly the basis for a blockbuster drug.

176. Solvay's extensive though troubled experience promoting estrogen replacement therapy and other hormone treatments gave the company an appreciation for AndroGel's potential. Beginning before launch, but peaking in late 2001, AndroGel brand managers, along with Solvay's vice presidents of sales and marketing, formed a strategy to focus, not on winning

[17] Jerome Groopman, *Hormones for Men*, The New Yorker, July 29, 2002, at http://www.newyorker.com/archive/2002/07/29/020729fa_fact.

market share from rivals, but on "making a bigger pie" by essentially expanding the definition of hypogonadism. Thus, Solvay engaged in a campaign to mass market AndroGel for "andropause," a supposed condition of male aging, as well as supposedly related ailments such as osteoporosis, sexual dysfunction (as a Viagra substitute), and depression, in male patients with both normal *and* abnormal testosterone levels, with *and* without clinical symptoms.

177. Ever thirsty for expanded sales, over the years Solvay adopted a laundry list of other off-label promotions, promoting AndroGel for "wasting" in HIV and AIDS patients, women, methadone and other opioid users, diabetics and those with "metabolic syndrome" (i.e. obese). By 2006, AndroGel had grown to be Solvay's top-selling pharmaceutical product, with U.S. sales of over $300 million. AndroGel became Solvay's top-selling drug and the chief asset on sale when Abbott Laboratories bought the company in early 2010. According to publicly-released IMS data, even as recently as the twelve-month period from June 30, 2008 to June 30, 2009, the testosterone replacement drug class increased sales by twenty-five percent, to over $840 million, with AndroGel leading the way.

(I) Prevalence of Hypogonadism

178. From the beginning, Solvay's marketing strategy relied on flawed, even deceptive observations about the likely prevalence of hypogonadism in American men; without these claims, all of Solvay's marketing schemes would have fallen apart.

179. Solvay launched AndroGel in 2000 touting the unsupported claim that four to five million American men suffered from hypogonadism. For this figure, Solvay cited the FDA's own website as the source, when in fact the figure came from the manufacturer of Androderm, a testosterone skin patch. Ex. 40 at KD00942. By 2004, as AndroGel became Solvay's bestselling

drug, testosterone treatment had skyrocketed to 2.4 million annual prescriptions—half of the so-called FDA prevalence figure and equaling the total number of men aged 40 to 69 in the United States whom the Massachusetts Male Aging Study (MMAS), released the same year, estimated were hypogonadal. *See* Andre B. Araujo, Amy B. O'Donnell, Donald J. Brambilla, et al., Prevalence and Incidence of Androgen Deficiency in Middle-Aged and Older Men: Estimates from the Massachusetts Male Aging Study, The Journal of Clinical Endocrinology & Metabolism Vol. 89, No. 12 5920-5926 (2004), *available at* http://jcem.endojournals.org/cgi/content/full/89/12/5920.

180. Solvay responded to the saturation of the market by adopting even more outlandish prevalence figures. In 2005, Solvay began relying on a yet-to-be-published study by Thomas Mulligan, a frequent beneficiary of Solvay funds. Mulligan's study, Prevalence of Hypogonadism in Males at Least 45 Years: the HIM Study ("HIM study"), which was eventually published in 2006, concluded that a whopping 38.7 percent, roughly 13.8 million, of American men over forty-five years of age seeing primary care doctors for any reason are hypogonadal, dwarfing the MMAS's estimated population. *See* HIM Study, *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1569444/ (coauthored by a Solvay employee). At one point AndroGel brand managers informed the sales force that according to physicians on its "Andropause task force," up to 20 million men might qualify as hypogonadal, if a "free testosterone" test, rather than a more basic total testosterone test, were used. Ex. 41 at SOLCID0076353 (2003 Brand Data Summary for AndroGel).

181. By 2006, Solvay's internal marketing presentations were reporting that the average length of time spent on AndroGel was by then only *four months*. Less than seventeen

percent of male patients were still on treatment after a year (incl[uding] re-starts). True hypogonadism in many men, including Klinefelter's syndrome sufferers, is a permanent condition. The figures on length of use (sometimes referred to disingenuously by AndroGel managers as "compliance" figures), suggest that Solvay's campaign to expand AndroGel's market was so successful that few patients taking AndroGel suffered from on-label classic hypogonadism.

182. Total testosterone tests are notoriously inconsistent; even performed at the same time of day, men with no symptoms of hypogonadism and no underlying condition connected with hypogonadism can test as abnormally low one day and normal the following day. Free testosterone tests are no better, but they do more frequently yield an abnormal result in older men.

183. In promoting these prevalence figures from the time of launch, Solvay took advantage of the difficulty in detecting accurate testosterone levels and encouraged broad screening. It bought the influence of prominent doctors and medical researchers. It disseminated a screening tool, the Androgen Deficiency in the Aging Male ("ADAM") questionnaire, which was actually designed to detect andropause, a controversial condition not accepted by the FDA, and not male hypogonadism. And it instructed its sales representatives to talk to doctors about symptoms and "low testosterone," or even better, "low T" rather than "hypogonadism." Accordingly, an HIV sales aid first introduced in January 2002, is entitled, "You're managing his HIV - Help him manage his low T." Similarly, a mid-2002 homework assignment from a Midwest Region sales representative suggested the close, "When a patient comes in and asks for Viagra, will you first screen for low T?" By supporting the prevalence figures it had

manufactured with these tactics and misleading language, Solvay was able to sell to physicians the notion that male hypogonadism was an American epidemic.

(II) Andropause

184. To create the figures to support the magnitude of silent epidemic that Solvay contended existed, Solvay promoted an expanded definition of hypogonadism. Solvay was and is marketing AndroGel for "andropause," a dubious medical condition for which the FDA has never approved the drug. Solvay has promoted this off-label use despite admonitions from the FDA in early 2000 that andropause, or "age-related hypogonadism" is *not* an approved indication. Specifically, a pre-launch letter from DDMAC dated April 12, 2000 to Unimed objected to the following phrases in a proposed sales aid: "'Age-associated' hypogonadal causes" and "Greater than 60 percent of men over 65 have free testosterone levels below normal values of men aged 30-35." DDMAC commented:

> Claims and representation that suggest that AndroGel is indicated for men with "age-associated" hypogonadism or "andropause" are misleading. AndroGel is indicated in males with primary hypogonadism or hypogonadotropic hypogonadism.

Ex. 43 at SOLCID0162634.

185. Solvay well understood the prohibition, and its regulatory department often disguised Solvay's promotion for "age-related" hypogonadism, by removing references to "older patients" from draft sales aids, and changing phrases like "is it age, or is it hypogonadism," to "is it part of life or is it hypogonadism?" As described below, however, Solvay continued to target older men experiencing symptoms of aging.

186. While the promotion of AndroGel for andropause began even before launch, AndroGel's sales exploded after the company focused more sharply on "educating" doctors

about andropause. In 2000, Solvay laid the foundation for sales by convincing influential specialists of an expanded need for testosterone supplementation. An outside consultant, EDU-Medical Management, Inc., issued a report to Unimed/Solvay in 2001 that stated, "It is understood, AndroGel cannot be promoted for off-label uses by Unimed Pharmaceuticals," with the apparent plan to take on that promotion on its client's behalf: its first "Medical Education Objective" was to "Create educational vehicles to identify age-related hypogonadism and showcase AndroGel® as the appropriate/ideal treatment option." Ex. 44 at SOLCID0070832, SOLCID0070833.

187. As part of that effort, Edu-Medical Management, Inc. declared in the same report that Solvay had already developed its own "consensus guidelines" for testosterone replacement therapy and planned to bring them to the Endocrine Society's 2001 Andropause Consensus meetings with the goal "to have them endorsed" by this supposedly independent group of specialists. *Id.* at SOLCID0070837. Solvay succeeded, thanks to pouring funds into the society's treasury and its board members' wallets; the Endocrine Society accepted the offer, along with an "unrestricted educational grant" in the amount of $139,482 to be used to produce a CME video entitled "Andropause Consensus 2000: Advances in Testosterone Replacement Therapy" as well as a CME entitled "Aging Men and Women: Does Sex Steroid Therapy Improve Quality [of Life]." Ex. 45. Various other physician events were planned. For instance, later in 2001, Solvay held "Physician Speaker Facilitator Workshops" to train over 300 regional urologists and endocrinologists to speak on the "importance of TRT and the critical role of Andropause." Ex. 44 at SOLCID0070842.

188. In late 2001, Solvay was ready to more fully capitalize on its educational efforts. It directed its sales force through flyers and at POA meetings that the goal for 2002 was "to grow the market. . . . Instead of going after a bigger piece of the pie, we need to make a bigger pie." Specifically, aimed to expand the testosterone market by a whopping 36.5 percent. POAII 2002 AndroGel Brand Data Sheet, Ex. 46 at SOLCID0074803. Primary care was targeted as the main source for such growth. Solvay made the linguistic move to "low T" at this time as well. "Peer influence" efforts were redoubled in 2002 to assist in the primary care sector. Sales from 2001 had been $115.8 million; by November of 2002, annual sales had already reached $164 million, and by the end of 2002 sales reached $188 million.

189. The "education" that Solvay provided to physician customers and speakers concerned the supposed existence of andropause and widespread need for hormone replacement therapy in men. Solvay noted the overall decline in testosterone among men as they reach old age and claimed that such a decline was not a "normal" part of aging but a disorder affecting strength, well-being, cognitive function, mood, sexual function, and other attributes, sometimes disproportionately or acutely, not unlike menopause. In early 2002, Marketing instructed the sales force to stop discussing "TRT," short for testosterone replacement therapy, and use the term "HRT" —"*His* replacement therapy," an allusion to hormone replacement therapy for women. Ex. 33 at KD00073.

190. Importantly, in identifying those supposedly suffering from andropause, Solvay applied the same normal range for testosterone to octogenarians that it did to twenty-year-olds. Then it applied a substantially overinclusive screening tool to identify men possibly suffering from hypogonadism. The Androgen Deficiency in Aging Males ("ADAM") questionnaire, still

in use today, asks questions that would make virtually every aging man a candidate for testosterone supplementation, such as:

- Do you have a decrease in sex drive?
- Do you have a lack of energy?
- Are you sad and/or grumpy?
- Are you falling asleep after (during) dinner?

See ADAM questionnaire, available at http://www.androgel.com/havelowt_quiz.asp#Quiz.

191. As the long title of the questionnaire indicates, however, the questionnaire was never designed to identify male hypogonadism. It was designed instead to identify "androgen deficiency in aging men," in other words, andropause or "age-associated" hypogonadism – exactly what the FDA warned was a misleading assertion in its April 12, 2000 correspondence.

192. Andropause is not only absent from AndroGel's label, but its possible existence remains the source of controversy and debate. It has never been listed in any drug compendium. The FDA has never approved a drug for treating andropause. The notion that sex hormones maintain or improve a person's health into old age has turned out to be a flawed one as applied to women, most famously with regard to the World Health Organization's estrogen replacement study, which was aborted early because of the prevalence of dangerous adverse effects. The facile way in which Solvay urged and continues to urge the same theory for aging men may endanger men's health in similar ways. In particular, steroid and testosterone use are associated with prostate or testicular cancer. Cardiovascular risk may also accompany testosterone treatment, particularly in older men. *See* Emmelot-Vonk, M. *et al.*, "Effect of Testosterone Supplementation on Functional Mobility, Cognition, and other Parameters in Older Men," http://jama.ama-assn.org/cgi/content/full/299/1/39; *see also* Basaria, S. et al "Adverse events associated with testosterone administration," N Engl J Med 2010, *available at*

http://www.nejm.org/doi/full/10.1056/NEJMoa1000485 (led by a Solvay-funded researcher, this study was recently halted early due to cardiovascular effects). In addition, many physicians believe that supplying supplemental testosterone to the body may cause the body to reduce its own manufacture of testosterone, perhaps permanently.

193. Dr. John E. Morley, the author of the study out of which the ADAM questionnaire arose and its creator, and his institution, St. Louis University, were beneficiaries of Solvay's largesse and partners in promoting the drug for years afterwards for the treatment of andropause through a national CME Grand Rounds series, and other programs. The Grand Rounds involved Solvay speaker events held in every region of the U.S., and dozens of speakers, including Drs. Ken Goldberg, Glenn Cunningham and Larry Lipschultz, all in Texas. Ex. 44 at SOLCID0070844-45. Morley has since received Solvay funds to study testosterone and renal failure as well as membership on Solvay's and Unimed's speaker's bureaus.

194. Coaxing physicians into screening patients through the ADAM questionnaire was crucial to Solvay's marketing plan, because positive results were frequent, and led either directly to an AndroGel prescription, or to a testosterone test. Indeed, testing strategies were also central to the marketing of AndroGel, as Solvay exploited the notorious unreliability of such tests in hopes of false positives. With older men, Solvay suggested, a free testosterone test was superior to a total testosterone test, the standard test, and particularly, if a total testosterone test came back in the low-normal range or the borderline hypogonadal range, a free testosterone test should be performed as well.

195. Relying on these strategies of heavy "screening and testing" allowed Solvay to cast an extremely wide net in fishing for patients; it segued easily into the promotion of

AndroGel to aging men with normal testosterone levels and men with "age-associated hypogonadism," despite the FDA's warnings.

196. Sales training materials circulated in July 2001 and adopted in the Mid-Atlantic, South, and Southwest districts, for instance, reflecting the company's nationwide marketing strategy, proposed that testosterone supplementation was necessary for the well-being of many aging men with normal testosterone levels. Those materials, authored by Tom Dovel, a Mid-Atlantic Region district manager, claimed that aging men need AndroGel when their testosterone level suddenly dips, even if it remains within the normal range. Ex. 47. "We can help write a new paradigm. One that captures both the andropausal male, as well as the hypogonadal male," the materials promised. *Id*. at K00537.

197. Perhaps, the materials posited, a man in his fifties was accustomed to a testosterone level of 1000, but experienced a sudden drop in testosterone that nevertheless remained in the normal range. Training materials urged that to *feel* "normal," that man needed to boost his testosterone levels. Representatives were told to ask doctors to look at how far a man was "*from the top of the normal range*, rather than how close he is to *the bottom of it*." *Id.* at K00538. As long as AndroGel treatment would not boost a patient's testosterone levels above the upper reaches of normal range, he was a candidate.

198. Accordingly, in December 2001, Tim Hatke, AndroGel Product Manager, directed sales representatives to deliver to physicians a CME video entitled "Andropause Consensus 2000: Advances in Testosterone Replacement Therapy" at the end of sales calls. Ex. 45. The video covered supposed andropause symptoms of decreased sexual desire, fatigue, and osteoporosis, as well as depression and advocated use of free testosterone testing, which would

yield a larger number of positive results than would total testosterone testing. The Endocrine Society, whose own coffers and most of whose members were recipients of Solvay grants or fees, created the video. A written CME package was also created, containing eleven articles, eight of which bear titles including "andropause" or other references to aging. Later, in January 2002, Solvay disseminated the Endocrine Society-endorsed consensus guidelines that Solvay's vendor had itself drafted and proposed, recommending a broader use of "testosterone therapy." Ex. 46 at SOLCID0074807.

199. Solvay speakers increasingly promoted AndroGel for andropause during this period. At a National Business Meeting in Las Vegas in January 2002, Dr. Larry Lipshultz of Houston, Texas, lectured the sales force on andropause. Handwritten notes from that lecture reveal that he suggested a "focus on aging" in marketing, noting the aging population of baby boomers, and advocated treating patients with borderline or normal testosterone with AndroGel based on symptoms, "not lab values." Ex. 48. In February, the Pittsburgh District sponsored two speakers at a West Virginia DO conference in Charleston, West Virginia. At that conference, Dr. Ninety-three, presented "Andropause and the Role of AndroGel" to around 120 physicians. Ex. 42 at K1084. Also in 2002, 4,500 doctors listened to Solvay's call-in audio-teleconference entitled, "The Aging Male: New Advances in the Treatment of Hypogonadism, presented by Dr. Adrian S. Dobs.

200. Speakers like San Antonio-based Dr. Ramon Perez first catapulted to nationwide speaker status in 2003 by pressing the envelope regarding "normal" testosterone levels. We know, for instance, from sales representative Stephanie Boeke's summary of a Perez presentation to thirteen professionals on May 26, 2004 in San Antonio, Texas, that Dr. Perez pushed the idea

that any testosterone level under 500 ng/dl should be treated, even though testosterone levels above 298 were deemed normal in studies appearing on AndroGel's label and in the medical community at large. *See* Ex. 49 at SOLCID102799 (June 25, 2004 "monthly report" from David Sharpe to Christa Townsend summarizing Perez talk); Ex. 50 (enthusiastic feedback from Perez talk on September 7, 2005). Dr. Fifteen, a cardiologist and high Medicaid AndroGel prescriber in San Antonio, Texas, became interested in speaking about andropause for AndroGel after attending a lecture in January 2004 by Dr. Seventeen on the subject, according to a July 25, 2004 monthly report from District Manager David Sharpe to Regional Business Manager Christa Townsend. Ex. 51 at SOLCID0102817.

201. For additional support in challenging definitions of hypogonadism, representatives were instructed verbally and in writing when "detailing"[18] doctors to rely on the American Academy of Clinical Endocrinologists' ("AACE") 2002 consensus guidelines. These guidelines discussed the potential treatment of men suffering from hypogonadism caused by "aging" with "low-normal" testosterone levels as high as 400 ng/dl, which was 100 ng/dl within the normal range as understood in the studies cited on AndroGel's label. The guidelines were circulated to the sales force with a cover letter warning representatives to use them promotionally, but *without* mentioning "andropause." Ex 52, *guidelines available at* http://www.aace.com/pub/pdf/guidelines/hypogonadism.pdf. While the cover letter made the point that Solvay had not funded AACE, at least two of four committee members for AACE at the time have long received Solvay funding: Dr. Ronald Swerdloff and Dr. Richard F. Spark.

[18] When a sales representative "details" a physician, often during a call to the physician's office, the representative makes his or her sales pitch concerning one or more drug for which the representative is responsible.

202. By 2004, as AndroGel's pump launched, district managers spoke and wrote openly to their supervisors and their sales representatives about changing doctors' perception about what is a "normal" T level, such as in this Mid POA II and AndroGel Pump Launch handout for sales representatives in 2004 that stated under "AndroGel® Core Message Strategy":

> Finally, as we discussed, find ways to change the doctor's perception of what's a 'Normal' T level, by discussing the AACE Guidelines and algorithm, and using Specialist peer influence, along with giving full disclosure of our indications and PI information.

Ex. 53 at SOLCID0100505. See also Ex. 54 at SOLCID0105658), Ex. 51 at SOLCID0102819, Ex. 55 at SOLCID0105469-70), Ex. 57 at SOLCID0106353 (monthly reports, field contact reports, and other Texas district documents dated 2004 to 2006 describing instances of probing doctors on what a normal testosterone level is, and of testing and treatment in borderline or low-normal cases).

(III) Andropause-related off-label uses: depression, osteoporosis, and sexual dysfunction/Viagra substitute

203. Representatives encouraged primary care physicians who were presented with middle-aged men complaining of various symptoms, such as depression or low sex drive, to consider low, borderline, *or decreased* testosterone levels as a cause and to prescribe AndroGel to treat the depression, *with or without prior blood tests showing abnormal testosterone levels*. Ex. 48 at D02481 (handwritten notes from lecture read, "For borderline low/normal T = treat symptoms, not lab values."); Ex. 56 at SOLCID065390 (Sales representative Jill Reed was observed in late 2004 asking Dr. Eighteen "What was the Total T level, and is he still going to treat this symptomatic patient if the lab shows low normal?").

204. Solvay convinced doctors that men with hypogonadism or decreased testosterone levels frequently suffered from depression-like symptoms; thus, if AndroGel helped the patient's

depression, low testosterone would be shown to be the underlying cause. Solvay developed, sponsored, and paid for a study on testosterone and depression, the Pope Trial, reprints of which sales representatives distributed widely. Ex. 58 (Pope trial). Sales representatives received comprehensive training on depression, mood, and physiological effects of low testosterone, even as they were told not to discuss the Pope trial. In fact, handwritten notes from a June 26, 2001 Southwest Regional POA II meeting show explicit instruction on making the pitch:

1. How are you treating depressed/moody men?
2. How is this working?
3. Do you ever have SSRI patients that have sexual dysfunction?
4. How would it be if you could eliminate that problem?

205. Other scripts for promoting AndroGel for depression circulated widely, too. Suggested probes included, "How are you treating your male patients who present with fatigue and depression?"; Ex. 47 (Mid-Atlantic region detail authored by Tom Dovel suggesting AndroGel for use in men not responding to SSRIs and men in their late 40's feeling moody, lethargic, fatigued, low sex drive). Similarly, a New Orleans district presentation concentrated on selling AndroGel to primary care physicians for men who fail on SSRIs.

206. Approved AndroGel sales aids were devoted to patients with depression. These sales aids referenced studies noting an effect of testosterone on mood. Yet Solvay admitted to its pharmaceutical representatives that the studies that supported improvement of depression through testosterone therapy only encompassed hypogonadal men. Ex. 47 at K00538 (Wang studies did not concern men in normal range). Solvay nevertheless used these inapposite studies to promote AndroGel for use in men in the normal testosterone range. Solvay marketed AndroGel for depression not just to primary care doctors, endocrinologists, and urologists, but

also to psychiatrists. In fact, Solvay developed an additional sales aid on depression just for this purpose. Ex. 60 (2000 routing approval sheet); Ex. 59 (specialty sales aid for psychiatrists.

207. Because Solvay advanced these unsupported claims that AndroGel was safe and effective in treating depression, depressed men with normal testosterone levels who received AndroGel were deprived of medically effective and legitimate drugs that could treat their depression. Perhaps more dangerously, depression can be linked to dangerous conditions such as cardiovascular disorders; treating the symptom in lieu of investigating underlying causes risked patients' health.

208. Solvay also promoted AndroGel as a treatment for the off-label indications of osteoporosis or risk of osteoporosis in elderly men with potentially low *or decreased* testosterone levels. In a summer 2001 program in Shreveport, Solvay speaker Dr. Glenn Cunningham, when asked "if any man with ANY sign of bone loss or bone mass decreases should be treated with AndroGel," "simply responded YES!!!" Ex. 61 (summary of talk disseminated to Southwest region). Solvay dedicated sales aids to this use as well. Solvay representatives and speakers pointed to data cited in AndroGel's label that suggested that supplementing testosterone in truly hypogonadal men was linked with increased bone density. Ex. 138 (AndroGel detail script from St. Louis District, stating, "The 10g dose of AndroGel has been shown to restore bone mineral density"). But even in studies that have found a positive correlation between testosterone levels and bone strength, testosterone levels accounted for only about five percent of age- and weight-adjusted differences. Moreover, men *with severely low testosterone levels* showed improvement in the spine, but no change was observed in the hips, which are the site of fractures that most commonly debilitate those with osteoporosis. Exposing elderly men to testosterone that

increased risks of prostate cancer and other disorders in exchange for this potential benefit to bone health was not only an off-label effort, but controversial at best for those without severe testosterone deficiency.

209. Solvay also promoted the off-label use of AndroGel as a substitute for Viagra in the treatment of sexual or erectile dysfunction. A 2001 AndroGel detail used in the Southwest region declared its plan to "Ride coat tails of Viagra and SSRI market." Ex. 63 at D02812; *see also* Ex. 62. During a January 2001 call, sales representative Ashley Thibeaux included this response to Dr. Nineteen's assertion that he had no use for AndroGel: "You must be the only doc in town that doesn't prescribe Viagra." Ex. 64. Solvay was undeterred by the limited or poor documentation demonstrating that AndroGel was effective in treating erectile dysfunction. Viagra was considered a competitor drug in this sector, and Solvay coached sales representatives to ask doctors to substitute AndroGel for Viagra, particularly when patients continued to complain of dysfunction after treatment with Viagra. Again, this marketing scheme placed patients at risk because patients did not receive effective treatment to determine the underlying cause of the sexual dysfunction, such as cardiovascular disease, which is much more highly associated with erectile dysfunction than is hypogonadism. Hypogonadal levels of testosterone are in fact associated with decreased libido, and not with erectile dysfunction, in all but the rarest and most severe of cases. Solvay was and is happy to blur the lines between these distinct medical problems, and continues today to promote AndroGel as a treatment for erectile dysfunction.

(IV) Use in women

210. Solvay also promoted AndroGel for use in women despite specific warnings on the drug's label that women must not use it.[19] Solvay sales representatives actively pursued obstetricians and gynecologists routinely placed by senior managers on representatives' target lists. Estratest, an older Solvay drug, non-FDA-approved and containing both estrogen and testosterone, proved handy for marketing to these doctors. Solvay representatives had already convinced numerous endocrinologists of the merits of Estratest and testosterone supplementation for increasing libido and well-being in women. The approach pitched to physicians was to treat symptoms; testing women's testosterone was not discussed or performed. It was simple to transition from Estratest to AndroGel with such physicians, now accustomed to supplementing testosterone without prior testing; they were already "sold" on the benefits for women (and easily coaxed to explore treating men as well).

211. To promote AndroGel's use in women, the company reworked an old non-branded brochure for women created to help drive demand for Estratest. The brochure was used by the Solvay sales force nationwide. Though non-branded, the sales force well understood the brochure's purpose; Tom Dovel, a district manager in the mid-Atlantic region, for example, expressly directed his sales representatives to use the brochure to detail physicians regarding the use of AndroGel in women. That brochure went through Solvay's usual internal review process when reworked in March of 2001; the routing sheet shows clearly that the brochure was meant for promotion of AndroGel. *See* Ex. 65 at SOLCID0074148 (brochure mark-ups); *id.* at

[19] The original 2000 label read under Contraindications: "AndroGel is not indicated for use in women, has not been evaluated in women, and must not be used in women." The same language appeared on the label until December of 2007, when it was omitted, leaving in place a contraindication for pregnant women, adding a contraindication for breastfeeding women. A new warning appeared on that label, stating: "Due to lack of controlled evaluations in women and potential virilizing effects, AndroGel is not indicated for use in women."

KD00989 (final version of brochure). The regulatory department approved the brochure for that use despite the warning on AndroGel's label that AndroGel "must not be used in women."

212. Furthermore, when Solvay Pharmaceuticals reprimanded sales representative Pia Nidiffer in 2003 for an AndroGel call on a doctor who treated only women, she responded that "everyone" promoted AndroGel to women, and others were not reprimanded. An internal Western region sales force newsletter from May 2002 reveals how casually Solvay's sales force engaged in such promotion; an article suggests better insurance coverage with, among other ICD-9 diagnosis codes, 256.3, which designates "Hypogonadism Female Hypogonadism Ovarian." Ex. 66.

213. Women normally produce testosterone in levels significantly lower than in men, and maintaining those levels is associated with libido in women, just as in men. But while testosterone supplements are sometimes recommended for women unable to produce testosterone, after full hysterectomy, for example, Solvay has never sought or obtained such an indication for AndroGel from the FDA, despite much post-launch talk that research would be forthcoming. Further, marketing AndroGel for women put such patients at risk, because testosterone therapy in women generally requires smaller doses than the AndroGel packaging allowed to be metered out, and the drug's labeling did not reflect full associated risks or directions for use. In particular, AndroGel was first packaged in small single-use packets. Sales representatives encouraged physicians to prescribe AndroGel to women and direct them to use a rough quarter of the pack at a time. The imprecise nature of the dosing was justified to physicians as a downside worth enduring because "anything's better than nothing" for women in need of testosterone supplementation.

214. Excessive testosterone in women produces serious adverse effects, such as acne, body hair growth, scalp hair loss, and a decrease in high-density lipoprotein (HDL) cholesterol levels, increasing the risk of heart disease. The balance between sufficient and excessive testosterone in women is a delicate one. An uncertain number of women likely suffered such adverse affects as a direct result of Solvay's marketing tactics.

(V) Laundry list of off-label promotions related to other target patient populations for AndroGel, including diabetes, HIV/AIDS

215. Recognizing that screening and testing of virtually any male population for "low testosterone" would lead to AndroGel scripts because of the overinclusiveness of the ADAM questionnaire and the unreliable nature of testosterone testing, Solvay has consistently aimed to expand the testosterone supplement market through identifying patient profiles with potentially higher incidences of hypogonadism and encouraging doctors to "screen, test and treat" these candidate patients. Solvay began by pursuing men over 45 years of age, HIV and AIDS patients, erectile dysfunction patients, and patients feeling fatigued or depressed as candidate patients that may be hypogonadal. By 2002, Solvay had incorporated a plethora of chronic illnesses, such as diabetes, abdominal obesity (sometimes referred to as "metabolic syndrome" or "MS"), chronic renal failure, rheumatoid arthritis, coronary atherosclerosis, and chronic liver disease, into its lists of target patient populations. Solvay was exploring promotion for treatment of chronic pain by 2003. In short, AndroGel had as many potential uses as snake oil.

Diabetes

216. Solvay's approved AndroGel print ads cited to the HIM study and stated, for instance, that diabetic men were twice as likely to have low T. In the field, however, marketing became more direct: representatives spoke about the difficulty of treating non-compliant,

overweight diabetic men and suggested that AndroGel could help manage, or even improve, patients' diabetes. Representatives claimed that AndroGel could increase such men's lean muscle, decrease their fat, get them moving off the couch, and, pointing in part to data on AndroGel's label that suggests that insulin therapy for diabetics may be affected by testosterone levels, potentially eliminate the need for some diabetes medications. It was Solvay's upper management that directed AndroGel to be marketed for the treatment of diabetes, but training was often indirect and discreet. A March 2006 Solvay Field Contact Report was more explicit: District Manager David Sharpe praised sales representative Laura Wheat for presenting the "diabetic message" to Dr. Twenty. Ex. 67. District managers gathered at national meetings for instruction in the sophisticated science related to diabetes necessary for making the pitch, which was delivered by trainers or opinion leaders. District managers then returned to their respective districts to train their own representatives. Ex. 67 at SOLCID0068262.

Obesity

217. Similarly, in the obese, it was claimed that AndroGel could reduce fat and increase lean body mass. In a January 2006 Solvay Field Contact Report, District Manager Kevin Maher observed that sales representative Twyla Jenkins needed to present the "fat Bob" piece when speaking with doctors.

Pain

218. Not only do men on long-term opioids experience a reduction in testosterone, but increasing testosterone could potentially supplement pain management, representatives suggested to physicians. Ex. 68 (November 4, 2003 internal memo on marketing AndroGel for pain, issued by Melanie Blanchard, product manager, calling the area "an opportunity for

growth"); *see also* Ex. 56 (one example of several Texas district reports discussing targeting of pain management clinics).

HIV/AIDS

219. Solvay has spent considerable resources marketing AndroGel to the HIV/AIDS patient population since AndroGel acquired a related orphan drug designation in 1996. But Solvay has never applied for an FDA indication for this use, apparently lacking the clinical support.

220. Immediately post-launch, Solvay began promoting AndroGel to treat AIDS wasting caused by a combination of food malabsorption, loss of appetite, and increased metabolism. Doctors sometimes prescribe steroids to HIV or AIDS patients with wasting to help replenish their lean muscle mass and body weight and improve physical endurance. Solvay used AndroGel's qualification as a steroid as the sole basis for marketing AndroGel as a treatment for wasting, lethargy and fatigue. In late 2001 or early 2002, Solvay actually created an AndroGel Specialty Sales Force that focused on marketing AndroGel to AIDS treatment centers. Ex. 63 at D02806.

221. Solvay's sales aids targeting this population consistently misstated clinical research and misled doctors about the prevalence of hypogonadism in those with HIV or AIDS in order to support routine screening and testing. The aids cited figures as high as fifty percent in the HIV population at large, even though the data supported only about a thirty-eight percent prevalence, and then only in the days preceding anti-retroviral therapy, when AIDS was widespread, with nearly all hypogonadal test results found among those with full-blown AIDS. Ex. 69 at KD00685 (sales aid entitled "Considerations for your male HIV+ patients"); *see also*

Ex. 70 (reprint of Dobs study entitled "Endocrine Disorders in Men Infected with Human Immunodeficiency Virus). Many HIV clinics began routine testosterone testing as a result, often setting a somewhat high 350 ng/dl as the lowest normal level, while others employed the ADAM questionnaire as a screening tool first, despite the existence of clinical studies that show its failure to detect hypogonadal patients in this population. As a result of these deceptive practices, AndroGel's use flourished, particularly among Medicaid patients in HIV practices.

c. AndroGel in DrugDex

222. Many of the off-label uses for AndroGel promoted by Solvay have not been listed in DRUGDEX and thus are not even arguably "medically accepted," such as andropause, diabetes, metabolic syndrome, and methadone/pain. Weight gain for HIV patients, the authorities for which were mostly Solvay-sponsored, was actually delisted between 2003 and 2008, apparently because of concerns about the listing. Certainly, DRUGDEX's 2003 edition misrepresented the 1998 Grinspoon article that it cites for that use, because it omitted the author's recommendation that patients should instead follow the exercise regimen that was also tested in the study, as discussed *infra* at VII(C)(ii)(d). Depression, the sole citation for which was a 2003 study by Solvay Luvox speaker Harrison Pope, was downgraded sometime between 2003 and 2008 and falls under DRUGDEX's middle category, with efficacy rated as "inconclusive," and the strength of recommendation now only "in some cases." In addition, the studies cited for sexual dysfunction were largely sponsored by Solvay, or authored by Solvay national speakers, and a third of the citations for osteoporosis were Solvay-sponsored. These conflicts of interest were not disclosed to DRUGDEX and/or do not appear on the faces of the authorities.

223. Other uses are listed but not supportive because of the conclusions of the research or its paucity. The listing for "menopause," for instance, was cited in the 2003 edition (and included in the 2008 edition as "hormone replacement therapy, postmenopausal") but the summary for the entry read, "Androgen supplementation in hormone replacement therapy is associated with negative effects on cerebral vascular activity and lipids but is beneficial in terms of sexual function." AndroGel is listed as "ineffective" for female osteoporosis. An anxiety listing is supported by a single case study of a hypogonadal man; its outcome has little predictive power.

d. Examples of False AndroGel Claims

224. Reviewing the Texas claims data reveals some clear examples of claims submitted and reimbursed by Medicaid for off-label usage and as a result of off-label marketing and kickbacks.

(I) Pediatric Use

225. Dr. Twenty-one, who was detailed at least eleven times from March 2001 to February 2002, prescribed AndroGel for Patient 52299****, an infant, on April 1, 2003. AndroGel has never been approved by the FDA for use in infants.

(II) Use in Women

226. Similarly, the FDA has never approved the use of AndroGel in women, yet an examination of the Texas claims data demonstrates that at least fifteen women enrolled in Medicaid were prescribed AndroGel from 2001 to 2005. *See* Ex. 71 (Summary chart listing the data for fifteen female Texas Medicaid patients prescribed AndroGel). One representative example of these prescriptions is an AndroGel prescription for a ninety-six-year-old woman to

stop supposed milk production after the birth of a baby (galactorrhea postpartum). Dr. Twenty-two in Brownsville, Texas, who was detailed thirty-seven times between March 2000 and February 2002, prescribed this drug for his 96-year-old patient three times between August and October 2004. Dr. Twenty-two prescribed AndroGel for another of his elderly female patients, a 93-year-old woman, for chronic airway obstruction on April 2002.

227. Two of the doctors who prescribed AndroGel for their female patients, Dr. Twenty-three and Dr. Eleven, were paid $250 each for participating in the Solvay City kickback program for Aceon. *See* Ex. 38 at SOLCID0011001. These doctors were then targeted for AndroGel. Dr. Twenty-three was called on twenty-seven times and detailed eight times from March 2000 to February 2002. He prescribed AndroGel for a female patient to treat premature menopause on January 1, 2003. Solvay sales representatives detailed Dr. Eleven sixty times from March 2000 to February 2002. She prescribed AndroGel for a female patient to treat urethral fistula on June 20, 2001.

(III) HIV

228. Solvay sales representative Arnold de la Fuente called on Dr. Twenty-four, who practices medicine with an AIDS clinic in South Texas, several times in 2004. Ex 72. In July of that year, de la Fuente showed Dr. Twenty-four the Kaufman CD, specifically slides on treating low testosterone in HIV patients. *Id.* De la Fuente gave Dr. Twenty-four copies of the ADAM questionnaire and encouraged him to screen all of his HIV and AIDS patients for low testosterone. *Id.* De la Fuente's efforts paid off, and in March and April 2005, Dr. Twenty-four wrote a Medicaid prescription for AndroGel for Patient 51179****, which was filled and reimbursed twice. *Id.*

(IV) Andropause and Andropause-related symptoms

229. As discussed above, Solvay marketed AndroGel for "andropause," as well as supposedly related ailments such as osteoporosis, sexual dysfunction (as a Viagra substitute), and depression. This was and is a successful campaign. For example, in 2005, Solvay sales representative Cheryl Kramer provided the ADAM questionnaire aimed at detecting andropause to Dr. Twenty-five. Ex. 73 at SOLCID0106361. In 2005, Dr. Twenty-five wrote three Medicaid prescriptions, all of which were for off-label uses (hyperpotassemia, renal and ureteral disorder, joint pain, lumbosacral neuritis, osteoarthrosis, and unspecified allergy). Ex. 74 (Summary chart of Dr. Twenty-five's prescriptions).

230. On September 7, 2005, Dr. Fifteen attended a speaker program given by Dr. Ramon Perez in which Dr. Perez encouraged the physicians in attendance to prescribe AndroGel to patients with testosterone levels in the low-normal range. From July 5, 2001 to July 8, 2005, Dr. Fifteen wrote forty-eight Medicaid prescriptions for AndroGel. Ex. 75.

231. Solvay targeted psychiatrists to receive the off-label message on the use of AndroGel for the treatment of depression. As a result, the following representative sample of Texas psychiatrists prescribed AndroGel for depression:

Patient Control Number (Redacted)	Diagnosis	Diagnosis Date	Medicaid Prescription Fill Date
19764****	Senile Depressive	8/31/2004	9/13/2004
19764****	Senile Depressive	8/31/2004	10/14/2004
40205****	Other Malaise and Fatigue	8/19/2005	8/22/2005
40414****	Generalized Anxiety Disorder	7/28/2001	10/24/2001
50074****	Depressive Disorder, Not Elsewhere Classified	1/15/2001	3/6/2001
50074****	Depressive Disorder, Not Elsewhere Classified	4/3/2001	5/3/2001
50343****	Anxiety State, Unspecified	8/4/2005	10/26/2005
50447****	Senile Depressive	1/13/2001	1/31/2001
50447****	Senile Depressive	1/13/2001	3/7/2001
50447****	Senile Depressive	1/13/2001	4/3/2001

232. A more complete summary chart of representative examples of doctors prescribing AndroGel for depression is attached as Exhibit 76.

233. A representative sample demonstrates that doctors also prescribed AndroGel for osteoporosis, a supposed symptom of andropause:

Patient Control Number (Redacted)	Diagnosis	Diagnosis Date	Medicaid Prescription Fill Date
40008****	Osteoporosis, Unspecified	6/27/2001	7/24/2001
40396****	Osteoporosis, Unspecified	1/6/2002	1/8/2002
40396****	Osteoporosis, Unspecified	1/6/2002	2/5/2002
50053****	Osteoporosis, Unspecified	11/2/2000	11/14/2000
50513****	Osteoporosis, Unspecified	9/5/2003	9/26/2003
50513****	Osteoporosis, Unspecified	9/5/2003	10/30/2003
50513****	Osteoporosis, Unspecified	9/5/2003	12/2/2003
50513****	Osteoporosis, Unspecified	9/5/2003	1/5/2004

234. A more complete summary chart of representative examples of doctors prescribing AndroGel for osteoporosis is attached as Exhibit 77.

235. A characteristic sample of the Texas claims data shows that Solvay's promotion of AndroGel for the treatment of sexual dysfunction, another supposed andropause symptom, was also successful.

Patient Control Number (Redacted)	Diagnosis	Diagnosis Date	Medicaid Prescription Fill Date
50033****	INHIBITED SEX EXCITEMENT	9/16/2002	9/16/2002
50065****	IMPOTENCE, ORGANIC ORIGIN	10/8/2003	12/26/2003
50065****	IMPOTENCE, ORGANIC ORIGIN	10/8/2003	2/19/2004
50065****	IMPOTENCE, ORGANIC ORIGIN	12/15/2004	6/10/2005
50122****	IMPOTENCE, ORGANIC ORIGIN	2/20/2002	3/12/2002
50122****	IMPOTENCE, ORGANIC ORIGIN	2/20/2002	6/28/2002
50122****	IMPOTENCE, ORGANIC ORIGIN	1/28/2005	4/21/2005
50122****	IMPOTENCE, ORGANIC ORIGIN	1/28/2005	7/21/2005
50138****	INHIBITED SEX EXCITEMENT	1/3/2001	2/5/2001
50138****	INHIBITED SEX EXCITEMENT	1/3/2001	3/8/2001

236. A more complete summary chart of representative examples of doctors prescribing AndroGel for sexual dysfunction is attached as Exhibit 78.

B. How Solvay Conveyed Off-Label Messages about Luvox, Aceon and AndroGel to Physicians

i. Sales representatives' and professional services associates' off-label promotion to physicians

237. Sales representatives acted as Solvay's front line in delivering off-label messages to physicians about all three drugs at issue here. Solvay's sales force is divided into various specialty groups, including primary care. Primary care sales representatives are typically responsible for marketing several drugs at the same time. Solvay required its sales

representatives to make frequent calls on doctors targeted by management using detailed prescribing data available commercially. The goal was to identify high prescribers within a product's drug class and high potential prescribers of the drug in addition to those already heavily prescribing the drug. High Medicaid prescribers were often included in such lists. To sell Luvox, primary care physicians, psychiatrists and others prescribing high numbers of mental health prescriptions were targeted. To sell Aceon, Solvay Pharmaceuticals targeted heavy ACE inhibitor prescribers among primary care physicians, nephrologists, cardiologists, and neurologists. Targeted AndroGel physicians include primary care doctors, gerontologists, endocrinologists, urologists, psychiatrists, and others, especially those prescribing high numbers of hormones, Viagra, or Cialis. The same high-level managers and executives at Solvay Pharmaceuticals' Atlanta headquarters who shaped the off-label schemes at issue assigned targeted doctor lists contained in electronic "DART" data (prescribing activity data purchased from an outside vendor) to districts and particular representatives on a semi-annual basis.

238. Luvox's promotion demonstrates how Solvay instructed its sales force to promote off-label. Every Solvay Pharmaceuticals sales representative, professional services associate, district manager, and regional manager was involved in the off-label marketing campaign for Luvox, because the essential sales needed for Luvox were off-label. Even the "core messages" for the drug were often off-label. For instance, the core message for 2000 was that Luvox was effective for "obsessions and compulsions" – there was no mention of OCD. Ex. 17. Brand manager Jack Redmond was similarly frank in 1996 explaining to the sales force the company's initiative to "expand the definition of OCD" beyond the FDA's definition of the disorder. Ex. 16.

239. Yet Solvay-approved sales aids and other materials subject to FDA scrutiny did not go so far as to overtly discuss the "OC Spectrum" or promote the drug explicitly for depression or anxiety. Neither did most of Solvay's more formal memoranda to its sales force, which resembled its sales aids. Solvay often reserved blatantly off-label communications with its sales force for closed-door sessions with smaller groups at regional and national meetings. There, sales representatives were taught how to avoid mention of OCD and provided effective scripts for promoting Luvox for depression and other uses, as discussed above in part VII(A)(i)(b). Rarely was this off-label training preserved in writing or by other means; the 1997 training video on Luvox and Lithobid survived by mere chance.

240. The company armed its sales force with off-label studies of Luvox, and with articles about the "OC Spectrum," but with a contrary admonition not to discuss such studies with physicians. In lengthy training sessions on Luvox's supposed effectiveness in treating pathological gambling, autism, and any manner of off-label indications, representatives understood that they were expected to relay such information to doctors, and that the admonition was delivered with a wink and a nod.

241. The sales representatives who understood the off-label training and promoted Luvox's uses for the "OC Spectrum," depression and anxiety had the opportunity to achieve higher sales, and, as with all of Solvay's drugs, Solvay rewarded those sales representatives and their district managers through its lucrative bonus structure, even when sales rose beyond those that could be accounted for by such a rare disease as OCD. In fact, Solvay's bonus structure rewarded and necessitated off-label sales for all three drugs.

ii. Shaping the Science through Medical Literature

242. Solvay paid influential doctors, termed "thought and opinion leaders" to research and/or write about the specific off-label uses that provided the most promise in terms of profits. Many of these payments took the form of large "unrestricted educational grants" that were anything but unrestricted.

243. Some grants supported research itself. Solvay's favorite Luvox researchers included Drs. Harrison Pope, Eric Hollander, Donald Black, John Greist, John March, John Walkup, and Charles Nemeroff (most of whom were on the Luvox Speaker's Bureau). Sponsored Aceon researchers included Drs. John Chalmers and Prakash Garg. Dr. Garg once received $25,000 to perform a study related to arterial wall compliance on diabetic patients. Drs. Christina Wang, Harrison Pope, John Morley, and Adrian Dobs, among others, all received research grants to study AndroGel.

244. Other grants, often to the same researchers, were for articles based on no new research. For example, in 1995 Solvay paid an "educational grant" to fund a symposium to be held with Dr. Eric Hollander as program chairman. Dr. Hollander was a proponent of the "OC Spectrum" concept so important to Luvox's success, especially in primary care, and a frequent recipient of Solvay funds. Both he and the symposium's host institution, Mt. Sinai School of Medicine, where Dr. Hollander served as Professor of Psychiatry, received fees and publicity from the arrangement. By choosing Dr. Hollander as chairman, Solvay was able to control the content of the symposium, which was held on September 20-21, 1995, in Augusta, Michigan, and was titled "New Frontiers in OCD Spectrum Research for Psychiatry and Primary Care." The materials presented at the symposium were later printed in the Journal of Clinical

Psychiatry. Solvay paid for similar symposia and articles for all three drugs throughout the years.

245. Solvay also sought out supposedly independent associations of specialists to issue "clinical practice guidelines" or "consensus guidelines" in favor of controversial positions that impacted its drug sales. Solvay's simultaneous lobbying and financial support of the Endocrine Society and its officers, discussed above, is an example. Another example dates back to 1997, when Solvay created its own "expert consensus panel" of sixty-nine OCD specialists (really a survey), headed by Solvay favorite Dr. John March, to publish "consensus guidelines." These guidelines unsurprisingly named Luvox as the "first-line therapy" for OCD, but also included the off-label section, "Guideline 10: Pharmacotherapy for OCD 'Spectrum' Conditions."

246. The resulting literature provided off-label selling points for sales representatives' detailing and for speaker program lectures, but more fundamentally, at the highest levels, it influenced the way medical debates bearing on the three drugs' profitability were framed. Once manufactured or funded, Solvay stamped an imprimatur on such medical literature by submitting it to medical compendia such as DRUGDEX. Because DRUGDEX imposes few or no editorial requirements for inclusion, the mere listing of a use or study can convey an air of legitimacy to the poorest scientific effort. As CMS has declared, a mere listing is therefore not "supportive" for purposes of rendering a use "medically accepted."

iii. Physician Speakers as Mouthpieces for Off-label Promotion

247. The success of Luvox, Aceon, and AndroGel hinged on off-label promotion, but because Solvay had to maintain plausible deniability for such promotion, it was difficult to rely entirely on its sales force to promote the drugs off-label. Solvay relied equally heavily on

physician speakers under its influence to deliver off-label messages for all three drugs. Sales representatives and professional services associates (sometimes called medical liaisons at other companies) played an integral role in disseminating off-label information through physician speakers.

a. CMEs

248. CMEs delivered by physicians were a frequently-used medium for off-label messages. Solvay sponsored and improperly influenced live CMEs relating to off-label topics, often given in conjunction with lunch or dinner. One example among many is a CME series launched to promote Aceon's PROGRESS results. In August 2001, Solvay provided an educational grant to third party CME vendor Curry, Martin, Schiavelli, Inc. to host a series of CME "Case Exchange" dinner meetings entitled "Evidence for Secondary Stroke Prevention: Findings from PROGRESS." The subject, of course, was the off-label PROGRESS study. Sales representatives in different districts received invitations to distribute to target physicians. Representatives controlled dates and restaurants and chose speakers from a faculty list. Attendees were then invited to fill out Case Study Forms for $150 honoraria (kickbacks) while at the event. Ex. 79 at D00964.

249. In 2002, Solvay paid $26,000 to the American Geriatrics Society, then affiliated with Dr. Thomas Mulligan, author of the HIM study. A return on investment form reveals that the money was for a single off-label CME Dinner in conjunction with Virginia Commonwealth University entitled, "Menopause and Andropause: What Do You Know and What Should We Do in 2002," at which Dr. Mulligan would serve as a paid speaker on "age-associated hypogonadism" and "subsets of the male population ("other than those that fall under the current

guidelines of being hypogonadal) that can benefit from testosterone replacement." Ex. 80 at SOLCID0072161.

250. Solvay representatives not only helped host CMEs, but frequently provided doctors with CME credit during calls by playing pre-recorded CMEs, typically on an off-label topic, and typically influenced by Solvay with regard to content and speaker choice, while feeding lunch to the doctor and the doctor's staff. Representatives commonly handled the application for CME credit on behalf of their doctors at these Lunch n' Learns, even filling out required quizzes on the contents of the CME.

251. Sometimes the CME was delivered on leave-behind CD-ROM's, such as the PROGRESS study CD-ROM, touting the benefits of Aceon to prevent secondary stroke. Sometimes CMEs were delivered by means of an audio-conference over the telephone. Solvay referred to this method as Instant Recall Audiotext (IRA) or "distance learning."

252. For example, as discussed *supra* at VII(A)(i)(b)(II), in 1996, Solvay developed a recorded Luvox IRA program that included talks on the OC Spectrum, pediatric use, and other off-label topics by Solvay "thought and opinion leaders." Ex. 15. In addition, over 4500 physicians listened in 2002 and 2003 to an AndroGel talk entitled, "The Aging Male: New Advances in the Treatment of Hypogonadism," given by Solvay-funded speaker and researcher Adrian S. Dobs. A presentation given at the December 2002 POA noted that this was a very successful program. The producer of the IRA program was INCE, Solvay's educational arm. Solvay was fully able to control the content of INCE programs, down the placement of a comma in a presentation, and did so. Solvay's Regulatory department, for instance, demanded revisions to a similar AndroGel CME to be delivered via CD-ROMs in 2003, including, as relayed by

AndroGel's associate product manager, the deletion of the phrase, "In the aging male," masking the presentation's andropause theme. Ex. 81 at SOLCID0032495.

253. Solvay often required its sales representatives to meet quotas regarding these in-office CMEs. For example, district managers required Solvay sales representatives to conduct at least two PROGRESS CD-ROMs per week. Solvay managers generally kept track of the number of IRAs that sales representatives completed. For example, in an e-mail dated November 29, 1999, Tom Dovel, Mid-Atlantic Region District Manager, praised sales representative Katheryn Lindsay for conducting twenty-one IRAs and Bill Riddick for conducting eighteen IRAs. Ex. 82. An analysis of the Southwest Region, most likely from the same time frame, recorded the number of IRAs that each sales representative completed. For example, sales representative VanLaere completed ten IRAs, and the sales representatives in the Dallas district averaged 6.1 IRAs completed.

b. Promotional speakers

Otherwise inaccessible high prescribers

254. Solvay conveyed off-label messages through promotional speakers as well. Solvay's promotional speakers included, among others, otherwise inaccessible high prescribers whom sales representatives chose as regional speakers mainly in order to have an excuse to "build relationships."

255. For instance, John King's first territory as a sales representative was in rural West Virginia – an economically depressed area with a high proportion of Medicaid enrollees. In his territory were two psychiatrists who were among the top ten mental health drug prescribers in the country according to Solvay's prescribing data. King was told that he ought to be a top seller of

Luvox given the presence in his territory of those two HVPs (high volume prescribers). His district manager, Chuck Christophel, directed by Regional Business Manager Lewis Stuart and National Sales Director Steve Jennings, advised him on how to get there. Of the two doctors, Dr. Twenty-Six was the eighth highest prescriber in the country. Dr. Twenty-Six began speaking to primary care doctors about Luvox for King at $750 to $1000 an event, and they became close over the next three years. Luvox began receiving five percent of his mental health volume, which was a feat. Most of Dr. Twenty-Six's events were scientifically insubstantial, but the speeches allowed King private time with Dr. Twenty-Six while driving him around, and allowed King to give Dr. Twenty-Six a substantial check.

256. A turning point with Dr. Twenty-Six came with a speaker's event at Princeton Community Hospital in Princeton, WV, in 1995 or 1996, at which he spoke with local psychiatrists and nurses. The event afforded King the opportunity to spend an hour each way driving Dr. Twenty-Six in his car, during which King was able to talk to the doctor about, among other subjects, the prospect of further speaking opportunities and honoraria. Over the course of the day, which included the drive, the event, and lunch, they developed a closer relationship. Before the event, 2.5 to three percent of Dr. Twenty-Six's prescriptions were for Luvox, but after that, Dr. Twenty-Six began prescribing four to 4.5 percent of his patients Luvox. King's success with Dr. Twenty-Six was one reason why he was asked to make the Luvox and Lithobid video.

257. King would often call on Dr. Twenty-Six at his office, and Dr. Twenty-Six's waiting room was always crowded with patients. The volume and profile of these patients was a frequent topic of conversation with both Dr. Twenty-Six and with his business office manager, with whom King would talk while waiting to see the doctor. Dr. Twenty-Six and his staff talked

about how he was a West Virginian who wanted to be there for West Virginians, and that he wanted to respond to the great need he perceived in his region. As a result, he saw an extremely high volume of patients a day and accepted all kinds of medical coverage, including Medicaid. He didn't care, as many doctors did, about his "payor mix" and how many of his patients had private insurance. Dr. Twenty-Six and his business office manager both spoke multiple times about the fact that many of the patients King saw in the waiting room on a given day were Medicaid enrollees. Others were entirely uninsured, and King knew from conversations with Dr. Twenty-Six and his staff that those patients were seen as well. Dr. Twenty-Six would try to supply them with sample medications in order to treat them without cost. King would leave whole cases containing 100 blisterpacks with Dr. Twenty-Six, as well as "stock bottles," to accommodate him, all with Solvay's encouragement. In contrast, he typically left only ten free Luvox sample packs with the other doctors on his circuit.

Coachable regional doctors

258. There were also "coachable" regional doctors recruited by sales representatives, some of whom became national speakers for Solvay. These speakers were often local specialists hired to speak to primary care physicians, such as urologists to tout the benefits of AndroGel, cardiologists to praise Aceon, and psychiatrists to recommend Luvox. For example, Solvay paid Duke University psychiatrist Dr. Twenty-seven $1000 to speak on Obsessive Compulsive and Spectrum Disorders at the Capitol Club in Richmond, Virginia on December 5, 1996. Richmond Psychiatric Society was the nominal host, but its name appears nowhere on the invitation. Ex. 83; Ex. 84. Solvay similarly paid Duke University-associated psychiatrist Dr. Twenty-eight

$2500 to speak on "From OCD to Social Anxiety: Managing the Anxiety Spectrum" at Silo Elevated Cuisine in San Antonio, Texas on August 30, 2000.

259. The sales force and professional services associates (PSAs) from Solvay's Professional Services Department typically developed promotional speakers. In a monthly report sent on February 1, 2000, for instance, to Ed Schutter, Solvay's National Sales Director of Primary Care Sales Force, and the district managers in the Southwest Primary Care Region, Tom Camp, a Solvay Regional Manager, discussed the development of local speakers in Kansas, Iowa, and Louisiana. Ex. 85 at SOLCID010994. PSAs were what many pharmaceutical companies called medical liaisons. They often had degrees – masters in a science, or registered pharmacists, or PhD's, and they had supposed impunity to provide off-label materials to physicians. Their job was to groom, and to provide all the off-label research, for physician speakers whom Solvay was developing.

260. In developing a speaker, PSAs would go to Marketing and ask questions like, "if you could have Dr. X Speaker say anything you wanted, what would it be?" The more coachable of the speakers developed by PSAs were used more frequently and rose to national ranks.

261. King was promoted to "regional marketing manager" (RMM) within the Marketing Department after three years as a sales representative. John King lived in Greensboro, North Carolina during this period, from 1997 to 1998. As an RMM, he was required to invent methods of selling rather than just the actual selling, including the creation of sales materials. His counterpart PSA was Kyle Kennedy. Kennedy found Dr. John Walkup at Johns Hopkins University, which was within Kennedy's territory. Kennedy described Dr. Walkup to King as

young, not yet a parent, able to travel, loves to golf. King and fellow regional marketing manager Tom Dovel would invite a group of psychiatrists and organize a speech. Afterwards, after a beer, Dr. Walkup would ask, "How did I do? Did I hit [such and such] hard enough?" And Kennedy and King would advise him to talk more about Xanax or panic disorder, based on what they were hearing in the field. Dr. Walkup was not shy about connecting Luvox to a number of OC Spectrum disorders. King and others could call Walkup in advance of a speaker's meeting also and talk about confirmed actual attendees and effective selling techniques for each. Soon Dr. Walkup's reputation for coachability became known throughout Solvay, and he was speaking at resorts like Grandview, staying busy most weeks.

262. Dr. John March of Duke University had also been developed by Kennedy, and he was also coachable and open to Solvay's feedback, though less so than Dr. Walkup. The major off-label area he would discuss was pediatric use and safety with children, an important Solvay message. When King was in West Virginia, Dr. Twenty-nine was the second highest prescriber of mental health drugs in the country. His practice teemed with out-of-work coal miners. From a sales representative's perspective he was generally unapproachable. At first Dr. Twenty-nine gave King and Luvox no scripts. Then Dr. Twenty-nine attended a lecture given by Dr. March at Greenbriar resort, and afterwards Luvox comprised about one percent of his scripts.

Opinion and Thought Leaders

263. Drs. March and Walkup eventually were accepted as national "opinion and thought" or "thought and opinion" leaders (OTLs). Other OTLs were physicians already prominent nationally, often researchers, whose support lent credibility to Solvay's off-label claims about the drugs; those speakers spoke on a national circuit, and sometimes lectured to the

sales force at national meetings as well. Solvay's Luvox OTLs included, in addition to Drs. March and Walkup: Dr. Charles Nemeroff from Emory, Dr. John Greist of the University of Wisconsin, Dr. Pedro Delgado of the University of Arizona, Dr. Eric Hollander of Mt. Sinai, Dr. Jack Gorman at Columbia University, Dr. Stephen Stahl from the University of California, San Diego, and others. They spoke live and sometimes in recorded lectures on topics similar to the off-label topics covered in the Distance Learning program guide. Ex. 15

Circuit riders

264. Particularly effective speakers sometimes traveled throughout a territory with a representative on a circuit of different speaking engagements. Typically, handouts and a meal were included. For example, Dr. Barry Hyman, a Houston internist and ophthalmologist, was delivering promotional speeches about Aceon around the Southwest region at least by 1999. Ex. 86. Tom Camp's February 1, 2000 monthly report to Ed Schutter and the district managers in the Southwest Primary Care Region noted that "We have seen a consistent pattern of prescribers on Launchtrack[20] having attended a speaker program with Dr. Hyman" and that "the representatives with most success has [sic] also had high frequency with the physicians who have attended speaker programs." Ex. 85 at SOLCID0010994. Later, in 2002, Dr. Hyman returned to the circuit to promote the PROGRESS trial results, delivering, for instance, a speech on that subject at the McGregor Clinic in Houston, organized by sales representative Dana Hargrove. Ex. 87 at SOLCID0174379.

265. At the same time as Dr. Hyman's 2000 travels, sales representatives and PSAs developed Dr. Michael Broder, a Montgomery, Alabama nephrologist who became a target upon

[20] Launchtrack was a tracking system by which sales representatives received the latest information on scripts reported by pharmacists.

Aceon's launch, into a regional speaker on the "diabetic kidney," and began making the rounds in the Southeast, adding Solvay to his other pharmaceutical sponsors, Astra Zeneca, Merck, and Pfizer. Ex. 88 at K00388 ("Birmingham District Speaker Funding Request June and July, 2000: Previously Committed Events"). Dr. Broder was considered an extremely effective speaker: in the spring of 2000 he spoke in four of nine territories in the Birmingham, Alabama district, resulting in twenty-one new Aceon target prescribers, including fifteen Montgomery doctors added in May, the month he began speaking there. *Id.* at K00389. In March 2001, the company's cardiovascular marketing department rolled out a live conference call speaker program with Dr. Michael Broder entitled, "Diabetic Kidney Disease and the Role of Ace inhibitors: An Inexorable Progression to ESRD [End Stage Renal Disease]."

266. In another example, from April 29, 2002 to May 3, 2002, Dr. Gerald Kumin took part in the "Kumin Ride Along" in which he spoke at several programs conducted at restaurants throughout Mississippi, including Hattiesburg, Gulfport, Forty-eight, and Ocean Springs. Ex. 89. Dr. Kumin's "Ride Along" included visiting physicians' offices with a different sales representative each day and speaking with these doctors about Aceon and the diabetic kidney.

267. Dr. Ramon Perez was another local speaker who became a popular regional traveling speaker for Solvay, eventually giving nationwide CME lectures, and speaking on AndroGel and expanded definitions of hypogonadism, as described above in Part VII(iii)(b)(II). Other regional AndroGel physician speakers have included Dr. Glenn Cunningham, who spoke on AndroGel and diabetes.

268. Solvay exerted little oversight over its speaker program and few uniform procedures existed. Some speakers received training on speaking or education on off-label

subject matter, while others received none. Some used company-prepared slides; some created their own. Regional speakers' fees were negotiated in a piecemeal way in each district.

C. Solvay Targeted Medicaid and Other Government Health Programs, Gained Formulary Access by Deceit and Other Means, and Caused Claims Arising from Such Tactics and Off-Label Promotions to Be Submitted for Payment

269. This illegal off-label promotion of Luvox, Aceon, and AndroGel to physicians resulted in scripts filled by pharmacies. The pharmacies then submitted such false claims to government health care plans, including Medicaid, Medicare, and TRICARE; in fact, Solvay went to great lengths to woo such plans and the physicians who treated the enrollees of such plans. Access to such formularies was important enough that Solvay was willing to conceal conflicts of interests, spread medical misinformation, and otherwise deceive government health programs and medical compendia like DRUGDEX in order to win that access. Furthermore, many of those who were not conspiring with Solvay were duped by the medical misinformation that it disseminated. Not only were such claims to government health programs tainted by that deception, but in many cases the claims were otherwise medically unnecessary or inappropriate.

i. Gaining formulary access through manipulating/defrauding DRUGDEX

270. Solvay fully understood that Medicaid and Medicare formularies do not encompass off-label uses for a drug without a supportive compendium listing. Accordingly, the company manufactured medical literature over which it maintained control in order to submit it to compendia and win access to Medicaid formulary coverage. An examination of the 1996, 2003, and 2008 editions of DRUGDEX as to the three drugs reveals authorities cited in support of off-label uses even where the sole authority cited, or the substantial support for the use:

- **actually failed to support the efficacy of the drug.** For instance, the PROGRESS trial is listed in Aceon's DRUGDEX entries even though it supports

only the accompanying diuretic's efficacy; the monotherapy arm of the trial failed.

- **was sponsored by Solvay and raises a conflict of interest.** An eating disorders study listed in Luvox's DRUGDEX entries for 2003 and 2008, authored by J.I. Hudson and Susan McElroy, was sponsored directly by Solvay. See Hudson, JI, McElroy, SL, et al, Fluvoxamine in the treatment of binge-eating disorder: a multicenter placebo-controlled, double-blind trial. Am J Psychiatry 1998; 155:1756-1762.

- **was sponsored by a Solvay-related company or company involved in co-promoting the drug and raises a conflict of interest.** For instance, the 2003 and 2008 editions of DRUGDEX list a panic disorder study supported by a grant from Reid-Rowell Pharmaceuticals, Inc. – a defunct Solvay company. Black, DW, Wesner, R, et al., A comparison of fluvoxamine, cognitive therapy, and placebo in the treatment of panic disorder. Arch Gen Psychiatry 1993a; 50:44-50.

- **was authored by one or more individual who has received Solvay funding and raises a conflict of interest.** For instance, the 2003 edition listed a study on compulsive exhibitionism conducted by Dr. Joseph Zohar, a frequent Solvay beneficiary and Luvox speaker. Zohar, J, et al. Compulsive exhibitionism successfully treated with fluvoxamine: a controlled case study. J Clin Psychiatry 1994; 55:86-88.

- **fell short of basic scientific research standards because it was not subjected to peer review, involved too few subjects, lacked controls, etc.** Luvox's listings for Asperger's syndrome and compulsive exhibitionism, for instance, cite only single case studies.

- **was actually authored in whole or part by a Solvay-affiliated ghostwriter, rather than the named authors**, a deceit on both DRUGDEX and probably the publisher as well.

271. In submitting DRUGDEX included these uses for Luvox, Aceon, and AndroGel, despite their lack of support, either because Solvay misled DRUGDEX about the attributes of these authorities, or because DRUGDEX colluded with Solvay, so that the uses listed might be deemed eligible for reimbursement under the various government health programs, especially Medicaid and Medicare. Alternatively, the listings result from a combination of both deception and collusion. Solvay openly communicated with medical compendia about its drug entries.

Upon information and belief, DRUGDEX learned about these inappropriate authorities through communications with Solvay, and Solvay chose not to disclose its financial ties to a study or author in submitting such authorities to DRUGDEX. Further, in submitting to DRUGDEX the PROGRESS trial results in support of Aceon, Solvay implied that the trial's conclusion was in fact supportive of the drug – that act of submission amounts to deception even if Solvay made no further attempt to describe the trial.

272. DRUGDEX also listed certain uses for which the FDA has specifically denied approval; the FDA denied Luvox a depression indication in both 1987 and 1994. In addition, the NDA for an adolescent approval for AndroGel has been delayed indefinitely; the FDA clearly is not confident about the company's current evidence of safety and efficacy. Other uses, such as kleptomania and weight gain in HIV/AIDS, have in recent years been retracted by DRUGDEX, without any apparent new research triggering the delistings.

273. Solvay's financial ties to the authorities listed in DRUGDEX are extensive. For example, out of twenty-two off-label uses listed in the 2008 edition of DRUGDEX under Luvox, twelve are supported only by studies with such financial ties, in many cases direct sponsorship, even after a sweeping delisting by DRUGDEX's editors. Only five entries are free of financial ties to Solvay. Some involve multiple financial ties. For instance, the 2003 edition of DRUGDEX listed just one study on the use of AndroGel to treat depression in men with low or borderline testosterone levels. See Pope HG, et al., Testosterone gel supplementation for men with refractory depression: a randomized, placebo-controlled trial. Am J Psychiatry 2003;

160:105-111. Not only did Unimed Pharmaceuticals, an entity owned by Solvay, support the study, but its author, Harrison Pope has extensive ties with Solvay dating back to Luvox days.[21]

274. One of Solvay's "thought and opinion leaders," Dr. Charles Nemeroff, whose depression study was used to detail doctors on Luvox and who served as Chair of Solvay Pharmaceutical Advisory Board, has recently been exposed for failure to disclose income from various pharmaceutical companies and signing ghostwritten articles actually drafted by pharmaceutical company personnel or their hired consultants. Whether Dr. Nemeroff engaged in such activities on Solvay's behalf is unknown, but Solvay was certainly no stranger to ghostwriting. As described above, EDU-Medical Management, Inc. wrote the consensus guidelines endorsed in 2001 by the Solvay-supported Endocrine Society.

275. Similarly, in October 2005, Solvay provided an educational grant to the University of Wisconsin for a CME delivered by Drs. Ronald Swerdloff, Christina Wang, and Richard Spark on "Testosterone Deficiency in Men." (CME program available online at http://www.jfponline.com/uploadedFiles/Journal_Site_Files/Journal_of_Family_Practice/supplement_archive/1005_JFP_testosterone.pdf). The lectures touted the benefits of testosterone and downplayed the risks. Solvay AndroGel Speaker Bureau members delivered all three lectures, two of which focused on aging men, the third on diabetes. The lectures were later packaged as CME articles. In conjunction with publication of those articles, Solvay paid about $1 million to fund University of Wisconsin-sponsored doctor education in 2005, 2006 and 2007 such as dinner

[21] As further examples, the 2003 edition of DRUGDEX listed a study on the use of AndroGel to treat sexual dysfunction in men authored by S. Arver, Adrian S. Dobs and A. Wayne Meikle. See Arver S, Dobs AS, Meikle AW, et al., Improvement of sexual function in testosterone deficient men treated for 1 year with a permeation enhanced testosterone transdermal system. J Urol 1996; 155:1604-1608. The 2003 edition of DRUGDEX also listed a study on the use of AndroGel for weight gain authored by Dobs. See Dobs AS, et al., The use of a transscrotal testosterone delivery system in the treatment of patients with weight loss related to human immunodeficiency virus infection. Am J Med 1999; 107(2):126-132. Both Dr. Dobs and Dr. Meikle are speakers for Solvay.

meetings around the country and newsletters designed to reach more than 50,000 physicians. See http://www.jsonline.com/features/health/52802117.html. Solvay hired for-profit medical education consultant Dowden Health Media to not only organize the events, but to participate in preparing the content of the lectures.

276. Solvay did not disclose to DRUGDEX (or government health program administrators) the nature of its financial relationships with and influence over entities such as the Endocrine Society or the University of Wisconsin. Solvay did not reveal the role of marketing consultants such as EDU-Medical or Dowden Health Media in its research activities. Nor did Solvay reveal even the status of its NDAs pending before the FDA. It was as a direct result of Solvay's deception and manipulation that Aceon, AndroGel and Luvox were able to gain the inclusion of a number of off-label uses in DRUGDEX in the hopes of rendering those uses reimbursable under government health care programs.

ii. Targeting and wooing doctors based on Medicaid/TRICARE/Medicare volume

a. Using Medicaid prescribing data to choose target physicians

277. In determining the doctors assigned as targets to each sales representative and each drug, Solvay managers specifically considered doctors' Medicaid prescription volume, relying on third party data. They then tracked sales representatives' calls on these doctors and the frequency with which these doctors were "detailed" on each Solvay drug. As a district manager, John King regularly received comprehensive data of this kind. In 2002, he received electronic data containing names of targeted doctors who had prescribed a Solvay drug at least once in Alabama, Arkansas, Arizona, Colorado, Florida, Georgia, Kansas, Louisiana, Mississippi, North Carolina, New Mexico, Oklahoma, Tennessee, Texas, Wyoming, and Utah

for 2000 and 2001 with regard to each drug. With such data, it was possible to run a report of targeted doctors who had prescribed Solvay's drug or a competitor to at least one Medicaid patient. From March 2001 to February 2002, for instance, 2,480 doctors who prescribed AndroGel at least once, and prescribed a testosterone supplement to at least one Medicaid patient, received sales calls.

278. Solvay sales representatives identified and called on their best Medicaid prescribers multiple times a year. In 2000, seventy-eight percent of Texas Medicaid's top Luvox prescribers, ninety-five percent of Texas Medicaid's top Aceon prescribers, and seventy percent of Texas top AndroGel prescribers were called on at least once by Solvay sales representatives. For example, Solvay sales representatives called on Dr. Thirty eighteen times, Dr. Thirty-one fourteen times, and Dr. Thirty-two thirteen times to discuss Luvox. Solvay sales representatives made calls regarding Aceon on Dr. Twenty-two fifty-three times, Dr. Thirty-three forty-two times, and Dr. Eleven thirty times. Solvay sales representatives detailed Dr. Thirty-four thirty-six times, Dr. Thirty-five twenty-seven times, and Dr. Thirty-six eight times on AndroGel.

279. In 2001, Solvay sales representatives called on sixty-eight percent of Texas Medicaid's top Luvox prescribers, ninety-eight percent of Texas Medicaid's top Aceon prescribers, and seventy percent of Texas Medicaid's top AndroGel prescribers at least once. For example, Solvay sales representatives made calls regarding Luvox on Dr. Thirty-seven sixteen times, Dr. Thirty-eight sixteen times, and Dr. Thirty-nine twelve times. Solvay sales representatives called on the following doctors regarding Aceon: Dr. Forty, 110 times; Dr. Forty-one, fifty-seven times; and Dr. Fifteen, forty-seven times. Solvay sales representatives

discussed AndroGel with Dr. Forty-two twenty-six times, Dr. Forty-three eighteen times, and Dr. Forty-four seven times.

b. Promoting Medicaid status to high Medicaid prescribers

280. Solvay encouraged district managers and sales representatives to find out about Medicaid's coverage of Luvox, Aceon, and AndroGel. At the June 2001 Southwest Regional POA II Meeting in Scottsdale, Arizona, brand management and the managed care department instructed district managers and sales representatives to educate themselves about Medicaid coverage of Aceon and AndroGel. A March 2002 business update for the Primary Care Central Region listed Medicaid formulary access as a competitive challenge. Ex. 91 at G-000907. A business plan by Jim Potter, District Manager for Nashville District, noted that opportunities for the district included getting formulary acceptance for Aceon on TennCare, Tennessee's Medicaid program. Ex. 92 at D02791.

281. District manager David Sharpe was all too aware of Medicaid status and its impact on sales; he used the prescribing data available to him to reassess strategy and designation of targets after Aceon lost its preferred Medicaid status in Texas in 2004, as reflected in an April 7 email to sales representatives. Ex 93. By the same token, with high Medicaid prescribers, Solvay used favorable Medicaid coverage as a selling point for all three drugs. Thus, in early 2005, Sharpe used the prescribing data to identify prescribers when AndroGel acquired favorable Medicaid coverage in Texas, with the thought that many diabetics on Medicaid were potential AndroGel patients. In April 2006, he advised sales representative Laura Wheat to take note that "Dr. Forty-five has 100 percent of Androderm scripts going to his

Medicaid patients" and to remind him that "AndroGel is on the Preferred Drug List of Medicaid," while suggesting different messages for other physicians.

282. As a further example, the Atlanta District 2001 Business Plan authored by Dan Gobat, District Manager of Atlanta District, Primary Care/Cardiology, advised sales representatives that when targeting physicians, they should focus on Medicaid patients and "Utilize Medicaid Stickers where appropriate," when distributing samples. Ex. 27 at K00462; *see also* Ex. 94 (Kentucky Medicaid stickers). Medicaid stickers, used in several states and approved at headquarters, were stickers that were affixed to sample boxes to remind physicians and their staffs of favorable Medicaid coverage. Similarly, in a February 2002 business plan, Drew Manning, District Sales Manager for Birmingham District, noted that the fact that Aceon had $2 co-pay and AndroGel has a $3 co-pay under Georgia Medicaid was "a routine part of our sales message." Ex. 95 at D02785.

283. In addition to the use of Medicaid stickers, Solvay drafted press releases and Medicaid Alerts to be sent to doctors, pharmacies, and patients regarding the status of Luvox, Aceon, or AndroGel on the Medicaid formulary. For example, one Medicaid Alert estimated that of 626,000 Kentuckians on Medicaid, 15,000 may have OCD, and listed on the alert prevalence of co-morbid depression or OC spectrum disorders, such as Tourette's and panic disorder. Ex. 94 at SOLCID0015265. A 1996 California press release noted that Luvox was now on all Medicaid formularies.

284. Some of the off-label disorders promoted by Solvay are disproportionately prevalent in Medicaid populations, as Solvay well knew. For example, Aceon's stroke prevention campaign focused on a potential patient population disproportionately within stroke

centers and nursing homes, and thus disproportionately covered by Medicaid. By 2001, the sales force actively sought out such stroke centers and nursing homes, as reflected in a November 14, 2001 email to sales representatives within the Southwest region. Anti-depressants are in frequent use in nursing homes too; Jeff Osmundson, a District Manager in Kansas City, favored nursing homes in particular in promoting Luvox. Ex. 11. Diabetes patients, targeted for both Aceon and AndroGel, are also especially prevalent in Medicaid populations.

c. Maximizing access to Medicaid

285. As discussed below in section VII(D), in states where Luvox, Aceon, or AndroGel require prior authorization, Solvay compiled lists of ICD-9 codes to provide to physicians in order to allow them to justify coverage for the drugs. Dr. Forty-six of Farmerville, Louisiana, himself a top Medicaid prescriber, worked with Solvay's Southwest region sales representatives and managers on a letter-writing campaign to create templates that doctors could mail to their stroke patients, urging them to make an appointment and learn more about PROGRESS and Aceon therapy. IMS electronic data supplied to King in 2002 reflects that Dr. Forty-six prescribed Aceon 1,548 times in 2000 and 2,501 times in 2001. There can be no doubt that among Dr. Forty-six's patients and others' patients who received such letters, some were on Medicaid. Additionally, Solvay prepared template letters to doctors and pharmacies regarding Luvox's status on the Medi-Cal formulary. Ex. 100.

286. Sales representatives sometimes offered inducements to doctors in order to access doctors' numerous Medicaid patients. For example, around March 2002, sales representative Rita Rizek completed a preceptorship with Dr. Forty-seven in Lexington, Nebraska, according to a Primary Care Central Region March Monthly Business Update. Dr. Forty-seven was chosen

because he treated a large Hispanic population with many patients who qualified for Medicaid — his patients were at high risk for diabetes and hypertension. In addition, two of the physicians in Dr. Forty-seven's group practice saw a large percentage of nursing home and elderly patients. *Id.* These targeting efforts were effective; in this same report, the Mid-Western district manager stated that "Dr. Ninety-four, a decile 10 nephrologist, has begun to use Aceon following a preceptorship done in February. Dr. Ninety-four has also begun to speak for Nebraska POD."

d. Wooing Medicaid P&T Committee members

287. Solvay also actively targeted doctors who were members of states' Medicaid pharmaceutical and therapeutic ("P&T") committees and pushed its off-label messages for its drugs in an effort to obtain placement of its drugs on the state Medicaid formularies. Nationwide, representatives and managers devoted great effort to learning what physicians served on P&T committees. Representatives sometimes offered preceptorships (i.e. cash) to physicians willing to disclose such members. Once a board member's identity was discovered, the sales force showered the member with offers of gifts, dinners, and every kind of bribe in exchange for hearing Solvay's off-label details. Such members often had no clinical practice, or specialized in a different area of medicine; they too received such treatment.

288. Nor was entertaining board members limited to launch periods for the three drugs; it was ongoing for fear that a favorable position on a preferred drug list would be lost or in the hope that an inferior position would be reversed. Wooing P&T committee members was discussed openly and earnestly on periodic conference calls with upper management. On one such call, Ed Schutter, Solvay's National Sales Director of Primary Care Sales Force, offered to meet in person with a committee member who was falling under Solvay's influence. On another,

management brainstormed about coaxing a committee member to have dinner by offering her a babysitter for her children. Once at dinner, or whatever event was chosen, committee members heard the same off-label messages that other physicians received from Solvay representatives.

289. Mike Bullington, Regional Business Director for the Central Region, covering Alabama, Mississippi, Florida, Louisiana, Arkansas, Tennessee, and parts of Texas, encouraged his sales team members to "wine and dine" these doctors, even doctors who never prescribed Solvay drugs or were retired. His district provides an example of Solvay's efforts to influence P&T committees. Other district managers were no different. In a February 2002 business plan, Drew Manning, District Sales Manager for Birmingham District, stated: "Working with State P&T chairman [for Alabama Medicaid] to have Aceon included on preferred ACE inhibitor list. Verified rebate status for Aceon, drafted letter to P&T chairman, waiting on Patrosky Lawson to OK." Ex. 95 at D02784.

290. A month later, in an e-mail, Jean Anderson, a Solvay sales representative based in Montgomery, Alabama, reported to Drew Manning, her district manager, that she had discussed Aceon and the PROGRESS study with Dr. Forty-eight, Chairman of the P&T Board for Alabama Medicaid, and had learned that Dr. Forty-eight favored Aceon for stroke patients because of the PROGRESS study. Ex. 101. Manning in turn forwarded this information to the Birmingham sales team and advised them to initiate discussions with doctors who were "big Medicaid writers" to determine if any of these doctors were influential with the Pharmaceutical and Therapeutic committee or any other Medicaid affiliate and solicit their support for Aceon as the drug of choice for Alabama Medicaid stroke patients.

291. Similarly, Jim Potter, District Sales Manager for Nashville district, discussed the issue of getting Aceon and AndroGel on TennCare's formulary in a business plan for his district. Ex. 92 at D02797. Potter noted that "I would like to see more contact with individual providers to get a P&T champion to present the product to the TennCare oversight committee." *Id*.

292. Sales representatives attended P&T committee meetings when permitted in an effort to obtain formulary placement. For example, Lou Ann Fare, a Solvay sales representative, argued for preferred status for Aceon based on the PROGRESS study at a November 2002 meeting of the West Virginia P&T committee. *See* November 19, 2002 minutes at http://www.wvdhhr.org/bms/sPharmacy/pdl/Mtg_agenda_minutes/bms_pdl_20021119minutes.pdf.

293. In September 2003, Solvay management approved a letter for an indigent HIV clinic and advocacy group in Miami, Union Postiva. According to the routing sheet, "The goal of the letter is for the President/CEO of this advocacy group to sent it out to case managers … as well as physicians that [sic] treat the HIV+ patients," so that they could in turn submit Prior Authorization forms urging Medicaid coverage. Ex. 96 at SOLCID0112624.

294. These efforts to include AndroGel on formularies for the benefit of HIV patients involved the same misleading promotion of AndroGel's supposed special benefits for HIV patients and same manipulated prevalence data that sales representatives were hoisting on physicians during that period. The letter contained language asserting that hypogonadism is present in about 30% of all HIV-infected men and 50% of men with AIDS, based on the same 1998 Dobs study cited in sales aids, which not only pre-dated anti-retroviral therapy but found

minimal hypogonadism among HIV-infected men without AIDS or other related symptoms, as described in Part XII(A)(iii)(b)(IV) above.

295. The letter also cited a study on the effect of testosterone on AIDS wasting among men with normal testosterone levels. This was obviously an off-label study, and Solvay was urging it on physicians and Florida Medicaid to support the treatment of AIDS wasting, not hypogonadism, but even more disturbing is Solvay's misleading description of the study as showing "significant improvements in muscle area and mass for subjects treated with testosterone compared to placebo." The study actually compared testosterone supplementation to weight training and concluded:

> In [this] era of highly active antiviral therapy, **patients with wasting are most often eugonadal** and [while they] have substantial muscle loss and muscle dysfunction, … they are generally stable and free of opportunistic infection. Although short-term administration of testosterone increases muscle mass, it may be associated with adverse metabolic effects in these patients. In contrast, our data suggest that supervised exercise training significantly increases muscle mass and offers cardioprotective effects by increasing the HDL cholesterol level in eugonadal men with AIDS wasting. Exercise may therefore be an ideal strategy to reverse muscle loss in these patients.

Grinspoon, S, Corcoran, C, and Parlman, K, et al., Effects of Testosterone and Progressive Resistance Training in Eugonadal Men with AIDS Wasting. A Randomized, Controlled Trial. *Ann Intern Med.* 2000; 133:348-355, *available at* http://www.annals.org/content/133/5/348.full.pdf+html (emphasis added). The study leaves little doubt as to why Solvay never applied to the FDA for an AIDS wasting indication; testosterone supplementation in eugonadal HIV-infected men is not worth the risks. Moreover, it also makes clear that there is no sizable population of hypogonadal men with HIV in need of AndroGel.

e. Targeting Physicians' TriCare, FEHB, ADAP, Medicare Part D, and other government health care plan patients

296. In several states, Solvay representatives also lobbied ADAP, supplemental state-run program offering HIV treatment to the indigent, for favorable formulary status. Letter-writing campaigns were not confined to ADAP lobbying: Solvay created three different templates to be used by physicians to lobby ADAP Administrators about adding AndroGel to their formularies. Ex. 103. Sales representatives were expected to recruit physicians to join such letter-writing campaigns. The templates cite and describe the very same studies as the Union Postiva letter, in the same misleading ways.

297. Further, Cherie Flynn, District Sales Manager in Virginia, noted in her 2002 self-appraisal that she had called on several Virginia ADAP P&T committee members on behalf of AndroGel. Dan Gobat, a Solvay sales representative, attended a meeting of the Texas Department of State Health Services HIV Medication Advisory Committee on September 24, 2004, during which the committee discussed adding AndroGel to the ADAP formulary. *See* September 24, 2004 minutes, *available at* http://www.dshs.state.tx.us/hivstd/meds/PDF/MIN-0904.pdf.

298. While that appearance was unsuccessful, and Texas's ADAP supplemental HIV program does not currently cover AndroGel, AndroGel was the thirteenth most popular non-antiretroviral drug for which enrollees asked for special assistance.[22] Twelve ADAP programs do cover AndroGel, and thus are surely paying for claims arising out of Solvay Pharmaceuticals' ubiquitous off-label marketing practices. *See* National ADAP Monitoring Project, *available at*

[22] *See* ADAP Partnership for Medication Access , Medicare Part D, available at . http://webcache.googleusercontent.com/search?q=cache:UIf6Bv69OPAJ:www.careacttarget.org/library/rw2008/Workshops/CAL-444_HaughtDTues1330Coolidge.ppt+partnership+for+medication+access+adap&cd=2&hl=en&ct=clnk&gl=us

http://www.kff.org/hivaids/upload/ADAP-Formularies-National-ADAP-Monitoring-Project-Annual-Report-April-2005.pdf.

299. Medicare Part D is increasingly important to Solvay with regard to AndroGel. AndroGel has obtained formulary status in various Medicare Part D programs, including Texas. Texas's ADAP supplemental HIV program recently moved 2,200 of its 15,000 clients to Medicare Part D.[23] Solvay has therefore aggressively targeted Medicare Part D business. In fact, Solvay put on a Medicare Part D internal marketing teleconference in March 2006. Further, Solvay prepared cards outlining formulary status to be distributed by sales representatives to high Medicare Part D prescribers. *See, e.g.*, Ex. 98. In February of 2007, when Silverscript, Caremark's Medicare Part D product, moved AndroGel to "tier two" status, District Manager David Sharpe instructed his sales representatives to aggressively target AndroGel prescribers who accept Silverscript. Similarly, a National Account Manager announced to the sales force on January 8, 2007 that United & Pacificare, the largest carrier of Medicare Part D lives, had selected Androgel as exclusive testosterone gel at tier two for 2007, and told the sales force to "work together to maximize our strength in the Medicare Part D marketplace."

300. Some of the claims submitted for patients within these ADAP and Medicare Part D programs inevitably arose out of the off-label marketing that has exaggerated the prevalence of hypogonadism among those with AIDS and claimed efficacy in treating AIDS wasting and other HIV-associated weight loss or weight distribution conditions.

301. Solvay has also identified and targeted doctors prescribing drugs to patients within other federal healthcare programs, including TriCare, the Federal Employee Health

[23] See footnote 22.

Benefit Program (FEHB), and Medicare Part D. For example, Solvay distributed TriCare targeted doctor lists to district managers and sales representatives. Ex. 104 (lists of targeted physicians—AndroGel and Aceon prescribers). Similarly, on May 31, 2006, Tim Stoops emailed his team about AndroGel's favorable coverage in the FEHB program and attached data regarding doctors who treated FEHB enrollees. Ex. 97.

D. Solvay's Widespread Use of Kickbacks

302. As a relatively small pharmaceutical company trying to gain market share in an increasingly competitive industry, Solvay lacked the clout to cut deals with prescription benefit management services and major health systems. Solvay compensated for its size by engaging in particularly aggressive physician marketing efforts. Solvay bribed doctors to use its drugs. Whether the kickbacks took the form of bogus speaker and research fees, resort weekends, cash payments, or Harley Davidson goods, the motive was the same—to lock in patient referrals (i.e. prescriptions). The recipients of these attentions were the high actual or potential prescribers on representative's target lists.

303. In addition to tainting those prescriptions that arose out of these schemes, Solvay's kickback strategy raised the total cost assumed by Medicaid because doctors, influenced by Solvay's remunerations, prescribed: (a) Solvay drugs that they would not have if not for the kickbacks; (b) medically unnecessary and ineffective drugs; or (c) more expensive Solvay drugs for which Medicaid ultimately paid.

304. Because Solvay's kickback schemes are intertwined with its off-label promotion of Luvox, Aceon and AndroGel, capturing off-label prescriptions for Luvox, Aceon and AndroGel captures not only the cost to Medicaid of Solvay's off-label marketing but also in many cases profits tainted by kickbacks.

i. Cash-for-Prescriptions Schemes

305. Solvay executives, managers, PSAs and sales representatives cooked up several kickback schemes in order to provide "incentives" in the form of cash to high-prescribers and to induce other physicians to prescribe high volumes of Solvay's drugs. Many of the cash schemes were variations on the same theme. For instance, one quasi-research theme was to pay doctors to fill out minimal paperwork on patients taking Solvay drugs, supposedly to further medical knowledge.

306. The sheer number of these schemes, their similarity, sales representatives' high level of discretion with their budgets, and the sparseness of the obligations imposed on physicians in exchange for the cash, point to the conclusion that these "programs" were mere incentives/rewards for prescribing Solvay drugs.

a. Speaker honoraria

307. The amount of speakers' honoraria, which varied and was negotiated on an individual basis by sales representatives, exceeded the fair market value and reasonable compensation ordinarily given to a speaker in a typical arms-length transaction, particularly as presentations were often short and the audiences small. For example, in May 2000, Solvay paid one doctor, Dr. Michael Broder, $10,500 in one month to speak to fewer than fifty people about Aceon, and over $100,000 for speaking engagements in 2000. Ex. 88; Ex. 105. Another doctor, Dr. Richard Aguilar, conducted three Aceon speaker programs on PROGRESS, costing a total of $5,314, on March 5 and 7, 2002. Ex. 106. From January to June 2001, the Southwest region spent $22,480 to conduct thirty-seven Aceon Peer influence events that 227 doctors attended. Ex. 107. Speakers were encouraged to speak at back-to-back events as often as several times a week, and no audience was considered too small.

308. Further, Solvay frequently held speaker programs at upscale venues or luxury resorts and invited and paid for the speaker's family to attend as well. Solvay's management encouraged representatives to select creative venues for speaker programs such as holding them at sporting events and dinner cruises. The occasion for such resort weekends could be a marketing feedback panel, speaker training sessions, a regional or district Advisory Board meeting, or simply a conference inviting high prescribers in the drug class to hear lectures on a particular off-label topic. Even where the lectures to be given were accredited CMEs, Solvay violated company-adopted AMA standards by paying doctors to attend, which it accomplished by issuing $100 gift certificates and/or paying for travel and lodging.

309. For example, on September 12 and 13, 1997, Solvay hosted the "OCD Spectrum Concept Advisory Panel" at the Homestead Resort in Hot Springs, Virginia. Ex. 141 (SOLVACID0011688 – invitation to event). Sales representative Jim Carroll organized the event, accompanied by Professional Services Associate Andy Hvizos. As the invitation promised, Solvay paid honoraria to the nine doctors in attendance. Doctors and their guests were also treated to fine dining and a choice of activities, including golf at one of the top-ranked courses in the country, horseback riding, spa treatments, and fly fishing. The weekend cost Solvay over $4,000.00, but its investment paid off. One attendee listed on the Homestead's lodging list, Dr. Ninety-five, became Virginia's third highest Luvox Medicaid prescriber.

310. Solvay employed the same tactics for AndroGel. For instance, Bert Stephens, Regional Sales Manager for the South Central Specialty Region, wrote a business plan for his seven representatives in 2001 in which he declared that he had "put aside $12,000 for each rep to

invite 2-3 key High Potential HIV writers of Testosterone [AndroGel] to a weekend program at a desirable location**."** Ex. 108 at K00482.

311. Such weekends were also organized out of headquarters: Solvay's brand management team organized a conference for HIV specialists to promote AndroGel, held on May 17 to 19, 2002, entitled, "HIV Issues 2002: Managing Side Effect Complications." Fifty-nine attendee physicians and six physician faculty members spent a weekend at the Phoenician resort in Scottsdale, Arizona involving six hours of meetings and plenty of time for golf and other "recreational activities," all paid for by Solvay. The off-label Saturday lectures promoted the use of testosterone, and, in particular, AndroGel, among HIV positive patients, and covered studies of such use in both eugonadal and hypogonadal men. Ex. 109 at SOLCID0070819.

(I) Speaker training workshops

312. Speakers often attended Physician Speaker Facilitator Workshops ("PSFW") or Speaker Training Meetings for which Solvay allocated $130,000 per program. An attachment to an October 8, 2001 e-mail from Shaji "Shawn" Durrani, Regional Marketing Manager-Cardiovascular for the South Central region, to the MTA-Field PC DM, Ed Maker and Michael Bullington contained the following description of these meetings:

> PSFW: A PSFW is a Speaker Training Meeting, identical to the ones which occurred in 2001. The cost of a typical program is $130,000, but cost may vary depending on your specifications. These meetings must fall in line with AMA guidelines and content is pre-determined by the home office. We recommend at least one of these per region in 2002. More than a few per region could be suspect, as one only needs so many speakers.

Ex. 110 at K00371. From January to June 2001, sales representatives in the Southwest region signed up four doctors to participate in the AndroGel speaker training program that Durrani described. Ex. 111 at K00645. Later in the year, sales regions apparently stopped worrying

about suspicion attached to selecting numerous doctors; by then, Solvay had held "Physician Speaker Facilitator Workshops" to train 291 regional urologists and endocrinologists to speak on the "importance of TRT and the critical role of Andropause." Ex. 44 at SOLCID0070842; Ex. 37 at SOLCID0093082. Solvay held similar trainings for Aceon and Luvox. In 1997, for instance, $170,000 was allocated for Luvox regional speaker training.

(II) Marketing Feedback Panels – Luvox, Aceon and AndroGel

313. Marketing feedback panels, or focus panels, were among Solvay's earliest and most abusive kickback schemes, used in promoting all three drugs. When Luvox was first launched in 1995, Solvay was a substantially smaller company with about three hundred sales representatives. Sales representatives would invite doctors from across the country to fly to a luxury hotel or resort and listen to speakers promote Solvay's new drugs. Solvay not only paid for each doctor's airfare and lodging, but paid each doctor an attendance fee to attend the speaker's program. To attempt to legitimize this scheme, Solvay representatives called the doctors "consultants," and asked them to comment afterwards on the effectiveness of Solvay's sales pitches. The Homestead resort event that promoted Luvox in 1997, described above, is an example of such an event.

314. Solvay also heavily relied on these feedback panels to promote Aceon when it was launched in 1999. In one Aceon launch event, Solvay sales representatives planned to host an estimated $2,300 focus panel for eleven physicians on March 18, 2000 at Grandover Golf Course in Greensboro, North Carolina, rated one of "America's Best Places to Play" in Golf Digest Ex. 111 at K00646. In 2000, sales representatives planned to host at least nine other focus panels at restaurants, with at least one including golf, in the Cape Fear, North Carolina

district in 2000. *Id.* Another typical destination for such luxury weekends was Hiltonhead Island in South Carolina.

(III) District or Regional Advisory Boards

315. Solvay also used district or regional advisory boards as a way to funnel kickbacks to physicians. Solvay would gather local physicians for the supposed purpose of providing Solvay with feedback on how to market its drugs. These district or regional advisory boards were open venues where off-label indications of Solvay's drugs would be discussed. In exchange for participating in these events, the physicians would each receive a fee or honoraria.

316. Durrani's October 8, 2001 email gave the following description of regional advisory programs for use in promoting AndroGel:

> Regional Advisory Panel: Physicians attending a Regional Advisory Panel are paid consultants. Too many of these programs could be suspect, as one only needs so many physician advisors. These programs will likely be conducted with the help of your Medical Liaisons. We recommend 0 to 4 per region, but you may do as many as you please.

Ex. 110 at K00371. Regional advisors were used to promote Luvox as well: a speakers list from 2000 identifies forty-five Mental Health Regional Advisors advising on Luvox, which would work out to 7.5 advisors for each of the six regions.

b. Dinner meetings with speakers and other speaker events

317. Solvay hosted multiple types of dinner meetings. No matter the type, these meetings often fell afoul of the Anti-Kickback Statute as well as OIG, AMA, PhRMA, and ACCME guidelines because they involved (1) sham consultants' fees for attendees, (2) met at entertainment venues, such as skyboxes at football games, or (3) involved spouses or children. *See* Anti-Kickback Statute, 42 U.S.C. § 1320a-7b; Department of Health and Human Services, Office of Inspector General ("OIG") Compliance Program Guidance for Pharmaceutical

Manufacturers, 69 Fed. Reg. 23,731 (May 5, 2003); PhRMA Code; AMA Opinion 8.061; ACCME standards. Some combined these attributes, any of which would alone be enough to violate the Anti-Kickback Statute as well as OIG, AMA, PhRMA, and ACCME guidelines. All of them routinely focused on off-label material to the extent that they had any substance or purpose beyond "relationship-building." In the months following Aceon's launch, for instance, Craig Kemerer, a Tampa sales representative, wrote a territory action plan that encompassed lectures squeezed between outings to Side Splitters comedy club, massages and saunas at the spa, Tampa Bay Buccaneers games, and the Nutcracker Ballet. With regard to the Nutcracker, Kemerer added the proviso, "(keeping in mind ROI [return on investment])." Ex. 112 at KD00492. Justifying costs to managers was a potential concern, but abiding by the Anti-Kickback Statute as well as OIG, AMA, PhRMA, and ACCME guidelines was surely not. Solvay held other programs at gourmet wine galleys and skeet shooting grounds – virtually any kind of entertainment venue was eligible. Solvay's venues and excessive compensation reveal that the focus of these speaker programs was on wining and dining doctors rather than on exchanging scientific and medical information.

318. Pampering doctors with expensive dinners caused attendees to prescribe Solvay drugs, including Luvox. On April 25, 2000, Solvay hosted a speaker program entitled, "Challenging OCD Cases" at the Post Oak Grill, an upscale restaurant in Beaumont, Texas. One attendee, Dr. One-hundred Two, wrote her first Luvox prescription for a Medicaid patient less than one month after attending the dinner program, and Medicaid paid for twelve Luvox prescriptions written by this doctor from May 16, 2000 to May 13, 2004. Ex. 131a. On April 28, 1999, Solvay hosted a speaker program entitled, "New Advances in the Diagnosis and

Treatment of Obsessive Compulsive Disorder" at La Scala, an upscale restaurant in San Antonio, Texas. Nineteen doctors attended the program, and five of those doctors started prescribing Luvox to Medicaid patients within a year.

319. Solvay also paid doctors to attend some of its dinner programs, which yielded multiple Luvox prescriptions from at least one attendee. On March 7, 2000, Solvay paid Dr. Ninety-six $250 to attend a regional dinner program, which had likely been planned in February 2000. Ex. 142 (SOLCID0010868). Dr. Ninety-six wrote his first Luvox prescription covered by Medicaid on February 15, 2000, and Medicaid paid for nineteen Luvox prescriptions written by Dr. Ninety-six from February 15, 2000 to November 12, 2001. Ex. 131a.

(I) CME Dinners and CME Case X-change - Aceon

320. Solvay routinely hosted CME dinners on off-label topics in promoting all three drugs. Especially in the early years, physicians were rewarded with a $100 gift certificate or other remuneration just for attending the larger of such events. John King explained Solvay's policy on such honoraria to his team in February 2000, for instance, with Regional Business Manager Rob Kunis's endorsement:

> As far as offering "honorariums" for docs to attend a program – this would be restricted to a Scienta Dinner program (national speaker) or a Focus Panel. The honorarium must be in the form of a gift certificate and should never be over $100. For the other programs, the event is the enticement whether in the form of food, books, gift certificates to be used at the event location (golf store, wine/cigar shop, plant store, etc.).

Ex. 113 at K00410.

321. Shortly after Aceon's late 1999 launch, Solvay created the "CME Case Exchange" program as part of its off-label campaign to promote Aceon as preventing secondary strokes. Physicians chosen for their high number of Aceon prescriptions were invited to a CME

event organized and controlled by Solvay at which a speaker would deliver the "Aceon message."

322. Initially, doctors were asked to appear at a kickoff event with a form filled out, describing a case study appropriate for Aceon's message for secondary stroke patients, and answering questions regarding whether Aceon was prescribed. Ex. 114 (CME Case Exchange Form). In exchange, physicians were entitled to $150 "honoraria" for every case study form submitted to Solvay. *Id.* In Dallas, one such event was given at a skybox at a football game. Solvay's stated purpose was for an editorial board to collect the case studies and periodically circulate a newsletter to participating doctors featuring particular cases to educate doctors about secondary stroke. But no newsletter was ever written or circulated, and no use was ever made of the information.

323. Solvay used the same strategy in promoting off-label uses for AndroGel, creating case exchange programs for AndroGel. Durrani's October 8, 2001 email described the AndroGel case exchange program as follows:

> Case Exchange: Case exchange programs are under development at this time, but will involve physician interaction and presentation of case studies. These programs will be similar to those conducted with ACEON in 2001. Our cost estimate for one of these programs is $4,500, but could vary. You may conduct as many or as few of these programs as you please."

Ex. 110 at K00371. These were effective programs. According to an Oklahoma City district business plan, "monitored attendees from [2001's] androgel [sic] case exchange are writing."

(II) Roundtables

324. An Atlanta 2001 district plan described Roundtable dinner meetings planned for Aceon this way: "These programs will feature a Regional Advocate (e.g., local cardiologist),

who is well respected for the selected therapeutic area. The format will include a short presentation and discussion lead [sic] by the Regional physician." Ex. 27 at K00464. That description conveys that the roundtable format was less formal than a traditional lecture, but fails to convey just how informal roundtables were. In fact, "roundtable" often meant "golf outing" or "skybox." Only with that understanding does it makes sense for a district manager to report in a field trip report, "Frank is developing some very strong relationships with his physicians, he was able to pull together an impromptu roundtable with 3 writers & their spouses in the Springfield area," or to refer to a "Golf Roundtable" in the same breath as a "Zoo Program." Ex. 115 at G-000855 (report of May 28-30, 2002 ride-along with representative Frank Garcia in Kansas City); Ex. 116 at G-000912 (March through April 2002 field trip report of ride-along with representative Michelle Thomas in Omaha).

325. During more formal roundtables, moderators sometimes used a PowerPoint presentation, but with an emphasis on discussion. Sales representatives spoke openly about steering the focus of roundtable to desired subjects. Ex. 112 at KD00491.

326. Roundtables sometimes became full-fledged resort weekends. For example, in 2000, Solvay hosted a speaker program on Aceon presented by Dr. Narenda Gupta at Beau Rivage, an upscale resort and casino in Biloxi, Mississippi. Ten doctors and their families were invited to share rooms, meals, and activities. Golf and a show in the evening were also planned. Ex. 117.

327. While Dr. Gupta spoke on arterial wall compliance, and arterial wall compliance and 24-hour control were the popular subjects in 2000, by 2002 Aceon roundtables were focused on PROGRESS. *Compare* Ex. 118 (district level use of Aceon roundtables in 2000) *with* Ex.

119 at SOLCID0049400 (Aceon Business Plan for 2002). Roundtables were popular among sales representatives for promoting AndroGel as well. In 2001, sales representatives chose respected urologists and endocrinologists who believed in AndroGel, and asked them after viewing the representative's target list, to choose four or five primary care physicians who refer to them. Ex. 120. $500 was the typical speaker's fee. *Id.*

(III) PR Supported Screening Event (CAST)- AndroGel

328. In promoting AndroGel, Solvay's brand management developed a series of $15,000 regional "CAST" programs to be held in 2002 designed to train doctors to drive press coverage. Program materials include a presentation on promoting AndroGel for sexual dysfunction and other uses, drafted by public relations firm Edelman Worldwide, which had also partnered with St. Louis University and Solvay to promote the ADAM questionnaire. The firm noted that topical stories, such as the FDA recent approval of sexual dysfunction drugs, may allow doctors "an opportunity to reach out to reporters and ensure they understand testosterone's role in sexual dysfunction and on libido." Ex. 121 at SOLCID0027469. Drs. Glenn Cunningham and David Kaufman served as "moderating faculty." *Id.* at SOLCID0027474.

329. By July 31, 2002, Solvay's district manager for the Kansas City District was reporting that three doctors had attended a CAST meeting in Topeka and that Solvay was now working on cultivating these doctors as speakers.

c. Preceptorships

330. Another Solvay kickback scheme involved preceptorships. "Preceptorship" describes an arrangement where a doctor allows a pharmaceutical representative to shadow him for part of a day (usually four to eight hours). During this time, the representative promotes and sells Solvay products to a captive audience. Solvay used preceptorships to market its off-label

uses to doctors. Indeed, Solvay mandated that its representatives participate in at least four preceptorships per month. In exchange for allowing the representative to shadow them, Solvay paid the doctors anywhere from $150 to $1,000. From January to June 2001, Tonya Stringer, a Solvay sales representative in the Shreveport District, participated in five preceptorships with Drs. Forty-nine, Fifty, Fifty-one, Fifty-two and Fifty-three. Ex. 107 at D00167. Similarly, the Atlanta Business Plan for January through June 2001 prepared by Dan Gobat set aside $800 per representative from the Aceon budget for four preceptorships per representative. Ex. 27 at K00470. Additionally, the Kentucky district set aside $1,000 from the Aceon budget for January through June 2001 for two preceptorships, and $4,500 for nine AndroGel preceptorships. In February 2000, in the Southwest region, Drs. Fifty-four, Fifty-five, and Fifty-six received $400, $500, and $750, respectively, in exchange for allowing Solvay representatives to participate in perceptorships.

d. Honoraria and Grants for Bogus Clinical Trials, Studies and Focus Panel

(I) ALERT Testing & Screening Program – AndroGel

331. Solvay and Unimed, a Solvay company, instituted this AndroGel screening program sometime before 1999. It continued until sometime in or before 2002. It originally involved a one-day screening event plus patient follow-up. Ex. 122 (ALERT Program Workshop presentation). The program was later extended beyond the one-day screening events, and representatives began to pay doctors in the form of a $500 "speaker's honoraria;" doctors continued to log new patients on Solvay screening forms, and representatives periodically collected the logs. A report on ALERT for first half of 2001 shows that the Shreveport district paid $16,500 in Alert "honoraria" and owed a further $22,000, with 397 patients screened –

nearly three times the original goal of 135. An example of a physician who received ALERT funds during this time is Dr. Fifty-seven, who apparently received $500 on May 11, 2001 for participating in a screening later that month. A completed ALERT patient log from one of Tonya Stringer's target physicians reveals that even patients who screened "negatively" received a testosterone test, and some of those patients were prescribed AndroGel. Ex. 137. Participating physicians, both specialists and primary care doctors, signed written agreements promising to advertise the screening event and to identify those among their patients who might suffer from hypogonadism. Ex. 138.

332. Under the ALERT contract, physicians were to be paid $500 upon "completion" of the program. For example, from January to June of 2001, Sales Representative D. Pallone placed ALERT kits with four different doctors, who screened an average of sixteen patients per doctor for a total of sixty-three patients. Ex. 107 at D00164. The four doctors had been paid a total of $1500 in "honoraria," with more funds requested as of the date of the report. *Id*. During the same time period, sales representative Tonya Stringer provided ALERT kits to twelve doctors, who screened an average of ten patients, for a total of 125 patients. *Id*. A total of $3,500 in honoraria was paid to these doctors. *Id*.

333. In addition, participating doctors and nurses were given pre-paid calling cards containing up to 20 minutes of free calls per patient, for up to 40 patients. Ten minutes could be earned per patient by reporting patients' symptoms, ADAM questionnaire results and giving a blood test. Ten additional minutes could be earned by reporting blood test results and any drug prescribed. Finally, Solvay also provided funds for doctors to advertise their screening events, and to cover the expense of adding the ADAM questionnaire to patient history forms. Ex. 122 at

D02487, D02490.

334. Physicians were told that Solvay would collate the content of the logs for a study, but the study never appeared. ALERT was in essence a plan to pay doctors for enrolling patients on AndroGel, as evidenced by Solvay's decision to pay doctors additional fees when they continued screening after the screening day was over, and physicians' expectation that further checks would ensue.

(II) Aceon Community Trial ("ACT") & REACT

335. Upon launch of Aceon in 1999, Solvay recruited and paid doctors to participate in what was billed as the Aceon Community Trial, to be published as a phase-four trial. Ex. 123 at KD00084. The program commenced with nationwide orientation sessions for targeted doctors at luxury hotels. The physicians were paid to attend the sessions. In addition, they were paid an initial payment followed by a second payment following enrollment for participating in the trial. Materials advertised ACT as "an open-label, community-based investigation of how well ACEON tablets controls (sic) blood pressure in various groups broken down by such variables as gender, age, and race." *Id.* Solvay set a goal of enrolling 2,000 physicians to enroll 10,000 patients, and to that end solicited 9,000 physicians. *Id.*

336. After the orientation sessions, physicians were required to turn in to Solvay various paperwork, including a signed agreement, a curriculum vitae, an IRS W-9 form (for payment), and a confidentiality agreement. Patients were put on Aceon and tracked for purposes of the study. Solvay repeated the promotion with "REACT," targeting 1,000 physicians who had never prescribed Aceon. Participants received free samples and "medical education." From January to June 2001, sales representatives in the Southwest region signed up ten doctors to participate in REACT. Ex. 107 at D00167.

337. Solvay eventually released a study report in some form. Nevertheless, Solvay saw ACT and REACT as essentially physician-enrollment programs. For instance, Rita Rizek, a sales representative in Western Nebraska, reported in her 2001 POA II Territory Business Review presentation that she was "winning" in terms of Aceon sales because of her recruitment of Dr. Fifty-eight and Dr. Fifty-nine for the REACT Trial.

(III) Aceon Physician Profile / Expert Interviews

338. Before Aceon was launched, representatives were asked to meet with doctors who prescribed high volumes of hypertension drugs. The thirty-minute interviews had the stated purpose of learning about the physician's practice and treatment of hypertension. In exchange for the interview, the physicians signed "Expert Interview Consultant's Fee Request Forms." Ex. 124. The representatives delivered $100 checks after launch of the drug, providing an opportunity to give these coveted doctors the full Aceon sales pitch. *Id*. In February 2000 in the Southwest region alone, twenty-seven physicians submitted to Aceon expert interviews, costing $11,150.

(IV) ACES Consultation Program – Aceon

339. Beginning in late 1999, Solvay entered agreements with doctors, initially from the Texas area, under which doctors would act as "consultants" on Aceon use. Ex. 125. On October 2, 1999, for instance, Houston District Manager Ed Rohrer circulated a list of over 250 physicians to be invited to participate in ACES. On October 18, 1999, Rohrer distributed materials to his team to launch the program, including a district advisory board agreement and patient tracking forms. Ex. 126. The Dallas and El Paso districts also participated in the scheme. Physicians were expected to "record blood pressure changes on a very modest number of Aceon treated patients over two follow-up visits," which information Solvay would compile

according to race, age and sex and distribute to participants on non-uniform enrollment forms created independently in each district. In exchange, Solvay would pay each "consultant" $100 per patient trial. Ex. 125. A patient trial required prescribing Aceon to a new patient, so this incentive amounted to paying $100 per script – a blatant kickback.

340. A PSA questioned the pilot program once underway, leading to cessation of the program and the termination of Ed Rohrer and Tom Camp, his regional business director. But this was no rogue program; rather it was a "pilot program." Ed Schutter, Solvay's National Sales Director of Primary Care Sales, was aware of the program from inception. Ex. 139 at SOLCID0000442 (Edward Rohrer performance appraisal for 1999, signed by Ed Schutter, referencing Solvay City and ACES programs).

341. After Rohrer's and Camp's terminations, sales representatives in involved districts clamored to get the checks they had promised their ACES physicians, and headquarters released the checks. Ex. 102. Arnie de la Fuente was one such representative; to obtain his physicians' checks, he forwarded to Human Resources signed consultant's agreements and patient tracking forms for Drs. Sixty (seven patients), Sixty-one (fifteen patients), Sixty-two (one patient), and Sixty-three (19 patients). *Id.* Other participating physicians included Drs. Sixty-four, Sixty-five, Sixty-six, and Sixty-seven.

(V) Solvay Interactive Representative Training Program (Solvay City)

342. In 1999, Solvay invited physicians to sign consultancy agreements under which physicians promised to listen to Solvay sales pitches for Aceon and provide feedback regarding their content and impact for up to two hours, in exchange for cash. At an initial dinner, Dr. Barry Hyman gave a lecture, and then sales representatives practiced off-label promotional

pitches, including "Arterial Wall Compliance" and "the diabetic kidney." Participating physicians filled out questionnaires gauging reactions to sales representatives' speeches. *Id.* at KD00698. In exchange, as their contracts specified, physicians were entitled to $250. Ex. 127 at SOLCID0011056. The physicians were not paid at the dinner, however. Instead, representatives told the physicians to go back to their practices and "get experience" with Aceon to allow them to serve better as consultants—i.e., prescribe Aceon. The representatives would "catch up" with each physician later, detail the physician on the drug, and then pay the $250. On February 9, 2000, the following ten high prescribers attended a Solvay City program: Drs. Sixty-eight, Sixty-nine, Seventy, Seventy-one, Seventy-two, Seventy-three, Seventy-four, Seventy-five, Seventy-six, and Seventy-seven. The following five physicians attended the same program on February 23, 2000: Drs. Seventy-eight, Seventy-nine, Eighty, Eighty-one, and Eighty-two. In February 2000 alone, $24,150 was paid to 128 doctors in the Southwest Region for participating in Solvay City program.

343. The Solvay City program also caused at least one attendee to prescribe Luvox. In February 2000, Solvay paid Dr. Twenty-three $250 for attending a Solvay City program. Ex. 144. Dr. Twenty-three wrote his first Luvox prescription for a Medicaid patient less than a month later, and Medicaid paid for thirty-four Luvox prescriptions written by this doctor between February 25, 2000 and August 22, 2003. Ex. 131a.[24]

344. Like ACES, this was a pilot program rolled out only in the Southwest region before it was discontinued. Like ACES, it was far from rogue, however. Sam Trujillo, Director of Cardiovascular Drugs, attended one of these meetings.

[24] Dr. Twenty-three was also an AndroGel target and prescribed AndroGel off-label for female patient, as discussed in paragraph 227, above.

ii. Non-Cash Kickback Schemes

345. In addition to the cash-for-prescriptions schemes, Solvay had other non-cash kickback schemes, as described below.

a. "Nurse Betty" Scheme

346. This was a program to promote Aceon and AndroGel that Solvay first rolled out in urban areas in the Southwest region in 2002, with plans to expand into larger areas incrementally, as announced in a March 2002 mid-POA AndroGel presentation to the sales force. Solvay hired nurses to work within doctor's offices for the sole purpose of identifying and screening patients for Solvay's drugs, primarily AndroGel. Doctors and their staff were freed from such screening, potentially allowing them to see more patients. Brand management discussed potential expansion of this program at POA meetings that Doe attended.

b. "Stock Bottles"

347. Solvay focused its distribution of drug samples on its top prescribers. Samples were in short supply, and in order to influence key doctors, when samples were in short supply, Solvay reminded its representatives that they should reserve "stock bottles" for the top 25 or "gold" physicians. Regional Business Director Christa Townsend told John King on February 14, 2002, that higher market share territories would receive "an ADDITIONAL supply of the stock pkgs." Ex. 128. Accordingly, when Solvay ran out of FDA-approved and labeled samples, sales representatives would repackage a stock bottle of 100 pills and divide it into ten smaller packages of ten pills and give them to ten different doctors in manila envelopes, thereby violating the misbranding and labeling laws, 21 U.S.C. Sections 331(b), 352(b) & (f), which

require that drug packages contain certain information not provided on Solvay's manila envelopes.

c. Lunch-N-Learns and other incentives tied to off-label sales details

348. Solvay conducted programs called Lunch-N-Learns for which Solvay representatives would bring in food from a popular restaurant for a doctor and his or her staff. During the lunch, representatives would play the PROGRESS CME on CD or would disseminate other information on the off-label uses of Luvox, Aceon, or AndroGel.

349. Lunch N' Learns were and remain a staple of Solvay drug promotion. The Kentucky district budgeted $25,200 for Lunch N' Learns for the first half of 2001, for example. Lunch N' Learns employed in promoting Luvox, Aceon, and AndroGel not only involved the provision of an item of value – a meal – in exchange for listening to a detail and ultimately writing scripts, but consistently concerned off-label topics.

350. Sales representatives sometimes set up Lunch-N-Learn speaker programs at local restaurants rather than offices, particularly when more than one doctor was invited. For example, On February 21, 2002, Dr. Gerald Kumin spoke at an Aceon Lunch-N-Learn on the topic of "Hypertension and the Diabetic Patient" in Little Rock, Arkansas. On March 5, 2002, Dr. Richard Aguilar spoke about secondary stroke prevention at an Aceon lunch in Lake Charles, Louisiana.

(I) Dine N' Dash

351. Dine N' Dashes followed the Lunch N' Learn model except in one important respect: the doctors took Solvay's free meals home to their families, which is strictly forbidden by the PhRMA code. Solvay representatives chose a popular restaurant and invited doctors to stop by to pick up dinner. Each doctor then ordered a take-out meal for the doctor's entire

family. While the doctor waited for the order, the sales representative gave a sales pitch on a Solvay drug. Solvay frequently chose expensive restaurants for Dine-N-Dashes. Solvay spent anywhere from $150 to $300 per doctor in feeding the doctors and their families. These meals were clearly for the doctor's personal benefit and conferred no benefit on patients.

352. As an example of a Dine N' Dash, on February 1, 2001, Solvay sales representatives Stuart McCown and John Burleigh organized an event involving detailing approximately fifty prescribers at Outback Steakhouse in Baton Rouge, Louisiana regarding off-label uses of Aceon and AndroGel. Dine-N-Dashes were popular forms of remuneration in Houston, too, because "they [] worked in a big way" there. Ex. 118.

353. From February to June 2000, sales representatives in the Cape Fear, North Carolina district set aside $13,350 for twenty-six Dine-N-Dash programs. Ex. 111. For example, on February 23, 2000, Solvay sales representative Bill Riddick from the Cape Fear territory planned to spend $1000 for fourteen doctors on a Dine-N-Dash at New Towne Bistro in Winston-Salem, North Carolina. Ex. 111 at K00646. Solvay sales representative Shannon Zeko from Cape Fear territory planned to spend $500 each on five Dine 'N Dash events, for a total of $2500, at various restaurants in Wilmington, Lumberton, Clinton, Whiteville, and Southport, North Carolina. *Id.*

354. In February 2000 Rob Kunis, Regional Business Director for the South Central region, approved a Dine N' Dash initiative in the Birmingham district, following successes in Houston and Raleigh during Aceon's launch. Kunis endorsed all of these suggested venues: restaurant, plant store, golf course, cigar store, car wash, bakery, pet store, computer store,

family ice skating at the ice rink, golf driving range, book store, wine store, florist, spa, movie theater, nursery, pottery store, music store. Ex. 113.

355. At least by 2002, pharmaceutical representatives from other companies understood Dine-N-Dashes to be what they truly were: kickback schemes. Solvay co-promoted AndroGel with TAP Pharmaceuticals at that time. On March 28, 2002, King emailed his TAP counterpart, Alvin Reine, about initiating a new series of roundtables with urologists as moderators and primary care physicians as attendees. Reine replied with a willingness to coordinate TAP's participation, but added, "I do need some clarification as I have heard that some Solvay reps are setting-up [sic] programs in which the doctors are able to take a meal home and I will state that TAP will not participate in any such programs as they are closely related to the dreaded "Dine and Dashes." Ex. 129.

(II) Book-N-Dash

356. For a Book-N-Dash, Solvay representatives would invite doctors to stop by a bookstore. Each doctor then received a gift certificate to the store. While the doctor waited for the certificate, the sales representative gave a sales pitch on a Solvay drug. For example, from February to June 2000, sales representatives in the Cape Fear, North Carolina district set aside $2,000 for four Book-N-Dash events. Ex. 111. Solvay sales representative Shannon Zeko hosted a Book-N-Dash at a Barnes & Noble in Wilmington, North Carolina on February 19, 2000, spending an estimated $500. *Id*. at K00646. Likewise, sales representative Phyllis Gordon hosted an event at Sloan's Book Shop in Waynesville, North Carolina on March 23, 2000 for an estimated $500. *Id*. at K00645. Solvay sales representative Austin Vaughn conducted two Book-N-Dash events: one on March 15, 2000 at Barnes & Noble in Greenville, North Carolina, and one on April 19, 2000 at Hasting's Books & Music in Rocky Mount, North Carolina,

spending an estimated $500 for each event. *Id*. Books-A-Million was a popular venue in the Birmingham district for similar events. Ex. 130.

(II) Flowers-in-a-Flash

357. The same scheme at a florist's shop was called Flowers-in-a-Flash. A Solvay sales representative would offer physicians free flowers at a local flower shop, particularly around special holidays, such as Valentine's Day. When the physicians came to pick up the flowers, the sales representative would take the time while the physician was waiting to promote off-label uses of Solvay drugs. These were popular events with physicians.

d. Gifts

358. In August 2000, David Neuberger, Senior Internal Auditor at Solvay America, sent a memorandum to Bob Solheim (Vice President of Finance and Administration), Ann Willmoth (Vice President of Sales), Barb Casey (Director of Training and Development) and Chip Dale (Controller and Chief Accounting Officer) at Solvay Pharmaceuticals and copied Morris Attaway, an internal auditor at Solvay America, and Phil Uhrhan, Vice President of Finance for Solvay America. Ex. 1. Neuberger's letter described an audit of the expenses of twenty sales representatives in the Southwest region incurred in promoting Aceon, which revealed a high volume of questionable expenses with regard to physicians. *Id*. Neuberger challenged many of the expenses claimed by Solvay Pharmaceuticals' contract sales representatives as inappropriate given the AMA guidelines' prohibition on physicians' acceptance of gifts of substantial value. *Id*. The July 2000 memorandum concluded, "We question if these 'serve a genuine educational function' and are appropriate." *Id*.

359. In complete disregard of the alleged company policy and the AMA guidelines, Solvay induced doctors to prescribe Solvay's drugs by seducing them with gift certificates to

their favorite stores of substantial value. Some examples of gift certificates offered in Texas found in Neuberger's audit are typical of the nationwide practice. For example, in February and March 2000, Solvay representative Shana Lodar gave Houston doctors gift certificates to restaurants in the amounts of $200, $300 and $625. *Id.* Similarly, an Austin representative gave a doctor a $203 gift certificate to a sporting goods store, Academy Sports & Outdoors. *Id*. Particularly egregious were the gift certificates for limousine rides in Houston and Dallas worth up to $700. *Id*. Solvay's practice of giving doctors gift certificates was plainly an attempt to pay for goodwill and induce doctors to prescribe Solvay's drugs.

360. Dating back to Luvox days, to induce more prescriptions, Solvay blatantly bestowed upon doctors personal items, often geared towards the doctor's specific interests or hobbies. Solvay frequently gave doctors tickets to entertainment events. Indeed, representatives would send doctors a photocopy of event tickets with a note stating that the tickets were available if the doctor would listen to the representative's pitch for two minutes. Ex. 140 at K00690. Thus, one Beaumont representative gave a doctor $930 worth of Houston Astros tickets, while a Houston representative gave a doctor $300 worth of Astros tickets. Ex. 1 at KD00706.

361. Similarly, Solvay representatives gave doctors a variety of expensive personal gifts ranging from spa packages, Harley Davidson jackets, bowling balls, big game hunting trips, hunting supplies, artwork, golf equipment, and coupons (to Starbucks and Blockbuster, among other stores). *Id*. For example, on March 15, 2000, a sales representative, William Coad, gave a $200 Eddie Bauer gift certificate to a doctor. *Id*. Another representative, Ashley Thibeaux, in

the Southwest region, spent $922 on a golf outing on March 15, 2000. *Id.* These gifts are just some of the remuneration Solvay paid in exchange for prescriptions.

iii. Examples of false claims arising from kickbacks

362. A representative sample of Luvox prescriptions written after doctors received kickbacks in various forms from Solvay is set forth below:

Physician Name **City/State**	**Remuneration Type and Date Received**	**Medicaid Patient Control Number (Redacted)**	**Diagnosis**	**Diagnosis Date**	**Medicaid Rx Fill Date**
Dr. Twenty-three	February 2000 Paid $250.00 honorarium to attend Solvay City program	50530****	Conjunctivitis and Convulsions	2/25/2000	3/6/2000 4/5/2000 5/5/2000 6/5/2000 7/3/2000 8/3/2000
Dr. One-hundred Two	April 25, 2000 Attended speaker program at the Post Oak Grill, an upscale restaurant in Beaumont, Texas	51402****	Attention Deficit Hyperactivity Disorder	5/16/2000	5/16/2000

Dr. Ninety-six	March 7, 2000 Paid $250.00 honorarium to attend a Regional Dinner Program that was planned in February 2000	50685****	Multiple Sclerosis	2/15/2000 2/25/2000 4/3/2000	2/15/2000 2/25/2000 4/3/2000
			Diabetes Type II	7/8/2000 7/22/2000 8/28/2000 9/12/2000 10/13/2000	7/8/2000 7/22/2000 8/28/2000 9/12/2000 10/13/2000
		51844****	Arthropathy	2/21/2000	2/21/2000
			Anemia	2/27/2001	2/27/2001
		51883****	Psychosis	10/30/2001	10/30/2001 12/10/2001 1/7/2002
				11/12/2001	11/12/2001 12/10/2001 1/7/2002 2/4/2002

363. A more complete summary chart of representative examples is attached as Exhibit 131a.[25]

364. Kickbacks resulted in Aceon scripts, too. By way of example, the following physicians prescribed Aceon after receiving some form of remuneration from Solvay.

[25] Exhibit 131a is attached and replaces Exhibit 131 to Relators' Third and Fourth Amended Complaint. Additional new exhibits, attached with this complaint, are Exhibits 141, 142, and 143.

Physician Name **City/State**	**Remuneration Type and Date Received**	**Medicaid Patient Control Number (Redacted)**	**Diagnosis Date**	**Medicaid Rx Fill Date**
Dr. Eighty-five Edinburg, TX	February 2000 Paid $250.00 for participating in Solvay City	51501****	5/24/2000 6/21/2000 10/5/2000 1/23/2001 5/3/2001 8/1/2001 12/28/2001 4/17/2002 7/30/2002 12/2/2002 3/31/2003 5/6/2003 10/17/2003 12/1/2003	6/22/2000 9/14/2000 12/5/2000 3/5/2001 7/2/2001 9/28/2001 2/25/2002 6/4/2002 8/1/2002 12/2/2002 4/1/2003 6/9/2003 11/3/2003 1/2/2004
Dr. Sixty-one Edinburg, TX	October 1999 Paid $1,500.00 for participating in ACES and placing 15 patients on Aceon	50099**** 50997****	12/7/1999 12/22/1999 1/5/2000 9/11/2000	2/1/2000 3/7/2000 4/3/2000 1/6/2000 9/11/2000 10/30/2000

365. A more complete summary chart of representative examples of doctors prescribing Aceon after receiving kickbacks is attached as Exhibit 132.

366. A representative sample of AndroGel prescriptions written after doctors received kickbacks in various forms from Solvay is set forth below:

Physician Name City/State	Remuneration	Medicaid Patient Control Number (Redacted)	Diagnosis	Diagnosis Date	Medicaid Rx Fill Date
Dr. Forty El Paso, TX	April 2001 Participated in REACT Oct 14 - 15, 2002 Received $3,000.00 honoraria/ speaker fees for two programs	50597**** 51952**** 50572****	Diabetes Mellitus Diabetes Mellitus Pure Hypercholesterolemia	4/25/2001 2/27/2002 10/1/2002	4/25/2001 7/24/2001 3/4/2002 4/6/2002 6/3/2002 10/2/2002 11/12/2002 1/13/2003
Dr. Thirty-three San Antonio, TX	February 2000 Received $1,200.00 honorarium/speaker fee for Aceon program	51421**** 51195****	Diabetes Mellitus Diabetes Mellitus	12/7/2001 8/3/2002	2/6/2002 8/3/2002

367. A more complete summary chart of representative examples of doctors prescribing AndroGel after receiving kickbacks is attached as Exhibit 133.

D. Solvay's Promotion of ICD-9 Codes to Obtain Reimbursement for Luvox, Aceon and AndroGel

368. Solvay compiled comprehensive lists of SSRI, cardiovascular, urogenital, and miscellaneous "related" ICD-9 diagnosis codes that it provided to doctors for the sole purposes of evading formulary controls and sometimes concealing actual uses in order to obtain

reimbursement for Luvox, Aceon and AndroGel, causing Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs to reimburse for drugs that were medically unnecessary. Solvay management, including Ann Willmoth, Solvay's Vice President of Sales, and James Prasch, Solvay's National Sales Director for Primary Care, mandated the promotion of these false codes by all field sales representatives. Solvay trained its sales representatives to distribute these codes to physicians, and other practitioners with prescribing privileges, and aggressively recommend their usage. Solvay sales representatives then coached physicians to submit these alternative diagnoses to Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs, suggesting codes for isolated symptoms and demonstrating with sample prescriptions, in order to get reimbursement for Solvay drugs that did not otherwise qualify.

369. Solvay's idea for the ICD-9 scheme for Aceon came from a presentation that Dr. Forty-six, who led the nation in Aceon Medicaid prescriptions, gave at the January 2002 National Business Meeting, in which he mentioned ICD-9 codes associated with vascular compliance. Regional Business Director Christa Townsend shared the idea with Jim Prasch to widely disseminate to representatives (and in turn to doctors) certain ICD-9 codes related to arterial wall compliance in order to get Aceon covered by managed care plans, including Medicaid. Prasch sent an email to Solvay's Marketing managers urging the promotion. Marketing included these ICD-9 codes in the Mid-POA marketing presentation for regional marketing managers as a suggested practice. Regional business directors were urged via

teleconference to spread the word to their district managers, and various (formally unapproved) flashcards were widely circulated in districts led by Tim Stoops, David Sharpe, Karen Franks, and Nancy Sutton Nau.

370. In February 2002, Jim Maxson, Regional Account Manager for Solvay, issued a memorandum providing a list of ICD-9 codes that sales representatives could offer as solutions to help achieve reimbursement for Aceon. Ex. 20. Following Maxson's memorandum, district managers provided the list to their sales representatives. The use of ICD-9 codes was a national scheme; for instance, in June 2002, Gary Fernandes, District Manager for West Chicago, reported in a June 2002 memorandum that utilization of Aceon ICD-9 codes was an initiative driving sales in his district that month.

371. In addition, several Illinois representatives discussed their success with the Aceon ICD-9 scheme during a 2002 or 2003 presentation. Eric McGinty stated that Dr. Eighty-six, a Kankakee, Illinois doctor and a large writer of Aceon prescriptions, "ha[d] been using coronary artery disease codes for his Medicaid patients and they ha[d] been going through." Ex. 134 at G-000036. McGinty stated that he "presented the 440.9 Atherosclerosis (unspecified) code to Dr. Eighty-six and he immediately used it with one of his Medicaid patients." *Id*. Dr. Eighty-seven, a Kankakee, Illinois nephrologist, had successfully used the 585 chronic renal failure code for Medicaid patients to allow patients to continue on Aceon and to start new patients on Aceon. *Id*. McGinty further stated that the nurse in Dr. Eighty-seven's office appreciated his willingness to fill out preauthorization forms for her use. *Id*. A year or two earlier in 2001, according to Solvay's prescribing data, Dr. Eighty-seven had written twenty-eight rival Ace Inhibitor prescriptions and 364 Aceon prescriptions. Solvay sales representatives called on him forty

times. Some of his Medicaid prescriptions in 2001, and at the time of the call described by McGinty, were likely for Aceon. *Id*.

372. In the same presentation, another representative, Damion Gibson, discussed his work with Dr. Eighty-eight, one of his "biggest Medicaid doctors on the south side of Chicago." *Id*. at 7. Gibson described how after Aceon was pulled from the Medicaid formulary, he went to talk to Dr. Eighty-eight and explained to him that he could still write Aceon for his patients. Gibson showed Dr. Eighty-eight and his nurse how to fill out the Medicaid Prior Authorization form, making sure to "explain to them that Aceon 4 mg is 'the only Ace I to have proven in it's [sic] P.I. that it increases Arterial Wall Compliance.'" *Id*. Gibson noted that "Since then, their office has had no problems with Medicaid Prior Approvals using ICD-9 code 440.9 (Atherosclerosis Unspecified)." *Id*.

373. Solvay also promoted ICD-9 code manipulation for AndroGel. For example, in an e-mail dated January 24, 2001 discussing the use of ICD-9 codes to obtain reimbursement for AndroGel, manager Kate Robertson wrote to Doe that "The best codes are the ones that reflect the symptoms, not the disease, such as ED [erectile dysfunction], Low Libido, Depressed Mood, Fatigue/Tiredness, etc." At a June 2002 POA meeting in Dallas, the specialty markets team that marketed AndroGel was told to stop promoting ICD-9 codes related to different symptoms purportedly associated with hypogonadism within the ADAM questionnaire. They were told to inform their primary care counterparts to do the same. When primary care sales representative Debbie Pallone reported this instruction to Christa Townsend, Townsend re-confirmed with Jim Prasch that the piece was permissible to use. It continued to be used. Ex. 24.

374. In late 2002, sales representatives were still encouraging doctors to use AndroGel ICD-9 codes. Ex. 135. For example, Dr. Eighty-nine and Dr. Ninety were ICD-9 Codes Advocates. Ex. 136 at G-000054. Both doctors prescribed only AndroGel among testosterone products and chose codes based on positive answers to the ADAM questionnaire. *Id*. at G-000054-55.

375. Solvay also encouraged its sales representatives to provide reasons for use of a non-formulary drug to aid physicians in filling out prior authorization forms. For example, Solvay encouraged Louisiana sales representatives to inform doctors that they could reference the PROGRESS study in the field on the prior authorization form as a rationale for using Aceon despite its "non-preferred" status. An August 2002 e-mail from Stanley Ferrell, Solvay Channel Account Executive for Eastern United States, warned Louisiana's sales team that Louisiana Medicaid did not approve Aceon for the preferred drug list and physicians were now required to submit prior authorization requests when prescribing Aceon. Ferrell suggested that the team inform doctors that they could reference the PROGRESS study in the field on the prior authorization form asking for a reason for the use of a non-formulary, or non-preferred drug, when prescribing Aceon. Ex. 99.

E. Retaliation Against King and Doe

376. King and Doe met when they both worked as District Sales Managers for Solvay. Each was responsible for supervising sales representatives who marketed Luvox, Aceon and AndroGel. In these positions, King and Doe were encouraged by Solvay executives to promote the use of off-label marketing campaigns for all three drugs. Both King and Doe were terminated by Solvay after questioning Solvay's practices.

i. John King

377. In late 2001, King was encouraged by Solvay executives to develop an off-label campaign for AndroGel. In response, he suggested enlisting local urologists to lecture about the off-label uses of AndroGel to primary care physicians. Soon afterward, overworked and increasingly unsure of the ethics and legality of the off-label promotions and kickbacks, King started discussing his concerns with his supervisors. He approached Mike Bullington, his regional director and direct supervisor, around Christmastime and questioned Solvay's marketing tactics. Bullington responded that King could put the noose around his own neck or fall on his own sword if he wanted to, but if Bullington were in King's position, he would keep his mouth shut and keep his own good job.

378. At the National Business Meeting held in January 2002 at Mandalay Bay Resort in Las Vegas, Nevada, King, determined to report his concerns, told Jim Hynd (Vice President of Marketing) and Steve Jennings (Business Director of Cardiovascular and Mental Health Marketing) that he was no longer comfortable with the marketing practices in which he, Hynd, Jennings, and the rest of the sales force were engaged. King had learned the word "kickback" during a company compliance lecture that he had attended, which had generally gone unheeded by employees. He used that word to describe how he, Hynd, Jennings, and the rest of the sales force were engaged in "illegal" activities, such as: (1) providing cash and gifts as incentives to prescribe AndroGel and Aceon; (2) providing, as part of the ALERT program, advertising money to doctors and compensating them for "Screening" on a per-patient basis; and 3) paying specialists to peddle Solvay drugs on off-label bases like PROGRESS through speaker programs.

379. King told Hynd and Jennings that he was worried that the company would "get nailed" for these tactics because they were not ethical or right. King said that he was tired of

participating in this kind of unethical work. Before both men walked off, Hynd commented briefly as he left that King "probably wanted to leave it alone." King called his wife that night and told her that he thought he had signed his own death certificate.

380. Throughout January and February of 2002, King discussed Solvay's illegal marketing activities regarding several of Solvay's drugs, including Aceon and AndroGel, with several Solvay executives, including Jim Prasch, National Sales Director for Solvay, and Christa Townsend, a Regional Business Director and King's immediate supervisor.

381. On March 30, 2002, King forwarded his finished AndroGel speaker presentation to his team, to Christa Townsend, his new regional director, and to TAP Pharmaceuticals, which co-promoted AndroGel. Townsend approved the materials. The presentation was generally lauded, and discussed as a piece that would be adopted nationwide to change the way AndroGel was pitched.

382. At the same time that King was voicing his dissatisfaction with Solvay's illegal marketing practices, King also discussed a health problem with a Human Resources representative at Solvay and the possibility of taking an "extended medical leave" as provided by Solvay. He opted not to take leave at that time, but on April 18, 2002, King's physician declared him "unfit to work," and King planned to take extended sick leave that he had earlier considered. He was denied this opportunity. On April 16, 2002, Jim Prasch announced briefly to King that he was suspended without pay for altering marketing materials. The allegedly unapproved materials were King's AndroGel presentation — materials that were actually approved by King's supervisors, Townsend and Kevin Porath, Regional Marketing Manager for Solvay and that were never circulated externally. Solvay claimed that King's reversal of two questions within the

ADAM questionnaire made the materials unapproved, even though the reversal had no effect on the questionnaire. Even after King's termination, for a time the sales force continued to use King's presentation.

383. Since his termination, King has been unable to find a position in the pharmaceutical industry.

ii. Jane Doe

384. In March 2000, Tom Camp, regional manager and Doe's supervisor, and Ed Rohrer, district manager, were terminated for their involvement in the kickback schemes, Solvay Cities and ACES, both described in detail above. Doe was aware that top-level sales leaders had sanctioned the scheme, yet observed as Camp and Rohrer became scapegoats. Several months later, Solvay America audited some questionable expenses incurred by Innovex contract sales representatives. As discussed in more detail above, the expenses, dating to 2000, included over $400 in limousine services for one doctor, upscale golf store goods, Harley Davidson goods, and other similar expenses. In response, Kyle Kennedy, Regional Business Director – Mid South Primary Care, and his supervisor, Ed Schutter, circulated the AMA's guidelines on spending on physicians via email.

385. On conference calls, Doe, along with Tim Stoops and Ed Schutter, discussed with Solvay executives questionable expenses dating to 1999 by contract sales representatives and how such expenses constituted "kickbacks." Undeterred by Doe's concerns, company culture remained unchanged. In fact, new schemes arose in the place of those that had been discontinued. High-level sales executives often consulted Doe, whose district earned consistently superior sales, for advice on marketing. Doe was asked to attend as a "field consultant" a number of quietly-held two-day conferences at Solvay headquarters in Atlanta led

by and attended by multiple vice presidents and high-level managers such as National Sales Director Tom Schenker. In late 2000 and early 2001, such conferences introduced tactics including evasion of formulary controls with ICD-9 codes, and the Nurse Betty program described above. Doe's advice was solicited on each scheme. Her dilemma was that she might get fired for speaking out, yet she might become a scapegoat if she remained silent. She chose to speak out in such meetings and specifically object that several tactics were illegal; she characterized these tactics as "incentivizing," essentially paying physicians to write more AndroGel and Aceon prescriptions. Each of her objections was overruled, and the practices were encouraged to continue.

386. Doe also questioned letter-writing campaigns. Solvay was soliciting physicians to write letters supporting adding Aceon and AndroGel to formularies, including state Medicaid formularies, on various company-suggested off-label grounds. Representatives then shared completed letters with other physicians to encourage them to write similar letters. During the same period, on conference calls with her superiors, such as Jim Prasch, to discuss the Aceon Case Xchange, a scheme to pay doctors $150 for every "case study" submitted on a new Aceon patient, Doe objected to the scheme and said that the payments constituted kickbacks. These practices were nevertheless recognized and applauded by upper management, such as Jim Prasch, as best practices and were encouraged to be duplicated nationally.

387. By late 2001, Doe, like King, had developed a reputation as a manager who questioned illegal company practices when asked to implement or promote them. Christa Townsend, Doe's immediate supervisor and soon to be King's, told Doe that she and King

"needed to play in the sandbox" better with others. Townsend sent Doe and King an email to the same effect at around the same time.

388. On July 23, 2002, Doe notified Solvay benefits representative Linda Hagood that she would be taking maternity leave with a projected return to work date of October 18, 2002. On July 25, 2002, Doe went on maternity leave for the birth of her child.

389. Doe became more outspoken over time about objecting to questionable practices. At last, while Doe was on maternity leave, in August of 2002, Doe complained to her supervisor, Christa Townsend, that she believed King had been wrongfully terminated and that his termination was based on something more than the reasons they had stated. She also complained that such a reason for termination, if legitimate, could put numerous people in danger of losing their jobs, including higher level, home office personnel, for doing or implementing the same activities. Doe discussed with Townsend her discomfort with company culture and her belief that Solvay was engaging in illegal and inappropriate activities. Townsend responded, "Why, what are you doing?" Doe named practices she believed to be illegal: ALERT, ICD-9 code manipulation, the letter-writing campaign, paying doctors to write, and other practices. Doe told Townsend that if King could be terminated after being congratulated year after year for his innovation, even while the same practices persisted, then Doe could be next. She told Townsend, "I feel like I may need to protect myself" through possibly consulting an attorney. Townsend downplayed Doe's concerns and told her she should have no worries. Townsend warned Doe to keep her nose out of such matters and not be so closely connected with King.

390. On August 2, 2002, Doe participated as instructed, although on maternity leave, in a mandatory telephone conference for all Southwest District Managers led by James Prasch and

Debbie Kishton, a Solvay Human Resources consultant. Typically, Solvay did not permit employees on leave to participate in such activities, but Kishton specifically requested that Doe stay on the line because the information was pertinent to her. Kishton and Prasch informed the district managers that any communication with a departed employee could be detrimental and damaging and could result in unfavorable legal action against Solvay. They also informed them not to offer recommendations and particularly to avoid using Solvay letterhead.

391. Concerned about the ramifications to the company, Doe immediately contacted Kishton and told her that she had been in verbal and written contact with King and had provided him with a written recommendation on Solvay letterhead to assist him in his job search. In addition, Doe had spearheaded a campaign to garner letters of recommendation for King. As a result, King was sent no less than ten letters from Solvay employees.

392. Shortly after the August conference call, Doe felt pressure to return from maternity leave early. On August 19, 2002, Doe e-mailed Townsend and Hagood that she intended to return to work from maternity a month earlier in mid-September as opposed to her original plan to return on October 18, 2002. Hagood asked Doe about this decision. Doe explained to Hagood that she felt that upper management was taking over her job and that she thought her job was in jeopardy and that Townsend was retaliating against her.

393. A few weeks later, Doe learned from a sales representative under her supervision that Townsend had held a telephone conference call on September 3, 2002, with all of the sales representatives in her region, to discuss the marketing campaigns. When Doe asked Townsend about the call, Townsend told Doe that she could not participate in the call. Townsend also indicated that she could not provide Doe with any further information about the call because Doe

was still on a leave of absence. Suspicious of Townsend's behavior and reasoning, Doe spoke with a sales representative on her team and learned that Solvay was investigating her for engaging in unapproved off-label marketing.

394. Worried that her job was in jeopardy, Doe began asking Townsend and the Solvay Human Resources department what was happening and if she could offer any input. On September 5, 2002, Solvay locked Doe out of her voicemail and e-mail. Doe learned from a sales representative on her team that Townsend had asked the sales representatives not to speak with Doe. When Doe questioned the Human Resources department about what was happening, she was told that she would need to obtain a physician's release to return to work before any information would be shared with her. Doe obtained a letter from her physician releasing her to return to work on September 5, 2002. The next day, Townsend, along with Mark Banks, from Solvay's Human Resources department, notified Doe that she was suspended with pay while they conducted an investigation regarding unapproved marketing materials.

395. From September 13, 2002 through September 16, 2002, Doe had various conversations with Townsend and others regarding their allegations of wrongdoing. Doe also provided documentation demonstrating that her actions amounted to common practice and were encouraged by upper management. On September 17, 2002, Doe met with Townsend and Kathy Frankel, a Solvay Human Resources representative. After supposedly reviewing all of the materials that Doe had sent in support of her actions, Frankel notified Doe at the meeting that she was terminated.

VII. ACTIONABLE CONDUCT BY SOLVAY UNDER THE FALSE CLAIMS ACT

A. Applicable Law

i. The False Claims Act

396. This is an action to recover damages and civil penalties on behalf of the United States and Relators King and Doe arising from the false or fraudulent statements, claims, and acts by Solvay made in violation of the False Claims Act, 31 U.S.C. §§ 3729–3732.

397. For conduct occurring before May 20, 2009, the False Claims Act ("FCA") provides that any person who:

(a) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

398. For conduct occurring on or after May 20, 2009, the FCA provides that any person who:

(a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim (except that this language applies to all claims pending on or after June 7, 2008)

(c) conspires to defraud the Government by committing a violation of the FCA;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

399. The FCA allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in federal district court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730.

400. Based on these provisions, Relators King and Doe, on behalf of the United States Government and the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, and Texas, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago seek through this action to recover damages and civil penalties arising from Solvay's causation of the submission of false claims to the federal and state governments. In this case, such claims were submitted to the federal and state governments for payment for Solvay's drugs, Luvox, Aceon, and AndroGel. Relators believe that the United States and the states have suffered significant damages as a result of false claims for payment for Luvox, Aceon, and AndroGel.

401. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the alternative, Relators are original sources as defined therein. Relators have direct and independent knowledge of the information on which the allegations are based. As required pursuant to 31 U.S.C. §§ 3730(b) and (e), Relators have voluntarily provided information, oral and/or written, and have sent disclosure statement(s) of all material evidence, information and documents related to this complaint, both before and contemporaneously with filing, to the Attorney General of the United States, the United States Attorney for the Southern District of Texas, the Attorneys General of the various states, commonwealths, the District of Columbia, and counsel for the City of Chicago.

ii. The Federal Anti-Kickback Statute

402. In pertinent part, the Anti-Kickback Statute provides:

(b) Illegal remuneration

1. whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

   (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

   (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

2. whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). A violation of the Anti-Kickback Statute is "false" for purposes of the FCA. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, codified as 42 U.S.C. § 1320a-7b(g). Those who violate the statute also are subject to exclusion from participation in federal health care programs, and civil monetary penalties of up to $50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

403. The purpose of the Anti-Kickback Statute is to prohibit such activities in order to secure proper medical treatment and referrals and to limit unnecessary treatments, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089 (proposed Jan. 23, 1989) (to be codified 42 C.F.R. pt. 1001).

B. Solvay's Violations of the FCA

i. ICD-9 Coding

404. Solvay management mandated that sales representatives inform physicians of psychological, SSRI, cardiovascular and urogenital "related" ICD-9 codes and coach these

physicians on submitting alternative diagnoses to Medicaid, Medicare Part D sponsors, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs for the sole purpose of obtaining reimbursement for Luvox, Aceon and AndroGel prescriptions. Physicians would then use these diagnoses and ICD-9 codes to submit prior authorization forms for Luvox, Aceon and AndroGel or to justify a prescription for Luvox, Aceon or AndroGel.

405. By advising physicians on the most efficacious ICD-9 codes and diagnoses to use for reimbursement purposes, Solvay knowingly caused physicians to submit false prior authorization forms and caused pharmacies to improperly claim reimbursement for drugs that were medically unnecessary from Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs. By taking part in this fraudulent scheme, Solvay repeatedly and with continued knowledge violated the False Claims Act, 31 U.S.C. § 3729(a).

406. Given the structure of the health care systems, false statements, representations, and records made, used, or caused to made or used, by Solvay had the potential to influence the government's payment decision.

407. Because of the illegal acts described above, Solvay made millions of dollars in sales of Luvox, Aceon, and AndroGel to patients it would not otherwise have achieved. The ultimate submission by physicians and pharmacists of false claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs was a

foreseeable factor in the government's loss, and a consequence of the scheme. Consequently, the states and the United States Government have suffered substantial damages.

ii. Solvay's Illegal Kickback and Off-Label Marketing Schemes Violated the FCA

408. Because of the illegal acts described above, Solvay made millions of dollars in sales of Luvox, Aceon, and AndroGel to Medicaid, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare program patients. Solvay violated the Anti-Kickback Statute by providing the kickbacks to doctors in the form of "honoraria," consulting fees, gift certificates, dinners, trips, flowers, and many other forms. The sheer number of these schemes, their similarity, and the sparseness of the obligations imposed on physicians in exchange for the cash, point to the conclusion that these "programs" were mere incentives/rewards for prescribing Solvay drugs.

409. Moreover, Solvay violated the FDCA by distributing drugs, specifically Luvox, Aceon, and AndroGel, that were misbranded; specifically, the drug labeling was false or misleading, did not bear adequate directions for use, did not bear adequate warnings against use in children and those with pathological conditions, and/or did not bear adequate warnings against unsafe dosage or methods of administration or application. Solvay's conduct also violated federal laws prohibiting a manufacturer from promoting off-label uses of its drugs. These off-label uses were not eligible for payment by Medicaid, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), or other federal healthcare programs because these off-label uses were neither "reasonable and necessary," nor "medically accepted." In addition, upon information and belief,

Solvay purposefully manipulated drug compendia, such as DRUGDEX, through the use of false statements or records or material omissions, and caused DRUGDEX in some cases to list desired off-label uses based on evidence that did not actually substantiate or fortify the uses with the intent of getting Medicaid, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs to reimburse these off-label uses.

410. Solvay knew that its false marketing materials, false and misleading representations and kickbacks by its sales representatives would induce doctors to write prescriptions for off-label uses or prescriptions tainted by kickbacks. Solvay also knew that its false marketing, fraudulent misrepresentations and kickbacks would cause physicians and pharmacists to submit claims for fraudulent Medicaid and Medicare Part D reimbursement. And physicians did in fact rely on Solvay's marketing misrepresentations. In fact, Solvay encouraged sales of Luvox, Aceon and AndroGel to Medicaid patients.

411. Once Medicare Part D was enacted in January 2006, Solvay actively promoted AndroGel's coverage on the major Medicare Part D plans and wooed doctors' Medicare patients. Andropause and related uses were a natural fit for this patient population largely over sixty-five years old, as were HIV patients moved over from ADAP coverage. The financial impact on Medicare Part D has been significant – the federal program has paid over $94 million on AndroGel since 2006. Among the top ten zip codes in which government costs for AndroGel have been highest is 77030, where Houston's Medical Center is located. These violations in the

law rendered the associated claims to the government not entitled to reimbursement.[26]

412. Solvay's fraudulent scheme to aggressively and illegally market its drugs for off-label use and integrate various forms of illegal kickbacks into its off-label sales campaigns led to increased prescriptions for its drugs. Virtually all off-label prescriptions for these drugs for which Medicaid, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs paid were a direct result of these illegal sales campaigns. Thus, these Medicaid, Medicare Part D, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare program claims for off-label prescriptions are tainted by the associated illegal kickbacks, as well as by Solvay's "mislabeling" of its drugs. Solvay's scheme violated the Anti-Kickback Statute and the FDA's prohibitions on the promotion of off-label uses, and therefore caused false claims to be submitted by physicians in violation of the FCA. By taking part in this fraudulent scheme, Solvay repeatedly and with continued knowledge violated the False Claims Act, 31 U.S.C. § 3729 (a).

413. Given the structure of the health care systems, false statements, representations, and records made, used, or caused to made or used, by Solvay had the potential to influence the government's payment decision.

414. Because of the illegal acts described above, Solvay made millions of dollars in sales of Luvox, Aceon, and AndroGel to patients it would not otherwise have achieved. The ultimate submission by physicians and pharmacists of false claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit

[26] The FDA reported on Medicaid utilization for AndroGel in 2009. That report is available at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM166697.pdf.

Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs was a foreseeable factor in the government's loss, and a consequence of the scheme. Consequently, the states and the United States Government have suffered substantial damages.

iii. Solvay Conspired with Physicians to Defraud Medicaid in Violation of the FCA

415. Solvay conspired with physicians to promote off-label uses of Luvox, Aceon, and AndroGel in violation of the FCA and to pay kickbacks to physicians in violation of the Anti-Kickback Statute to induce physicians to prescribe high volumes of Luvox, Aceon, and AndroGel. As Solvay knew would be the case, Solvay's actions resulted in the submission to state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs of false and/or fraudulent claims for reimbursement for Luvox, Aceon, and AndroGel, violating the FCA, 31 U.S.C. § 3729(a).

416. Given the structure of the health care systems, false statements, representations, and records made, used, or caused to made or used, by Solvay had the potential to influence the government's payment decision.

417. Because of the illegal acts described above, Solvay made millions of dollars in sales of Luvox, Aceon, and AndroGel to patients it would not otherwise have achieved. The ultimate submission by physicians and pharmacists of false claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs was a foreseeable factor in the government's loss, and a consequence of the scheme. Consequently, the states and the United States Government have suffered substantial damages.

iv. Solvay Retaliated Against King and Doe in Violation of the FCA

418. Solvay took negative employment actions against King and Doe in response to their questioning of the legality and ethics of Solvay's off-label marketing schemes. At first, this negative action took the form of criticism. After King and Doe continued to question Solvay's conduct, Solvay terminated them in 2002. Because of Solvay's conduct, King and Doe suffered negative employment consequences and have suffered damages, now and in the future.

VIII. Damages

419. Under the FCA and applicable laws, Luvox, Aceon and AndroGel prescriptions resulting from these false and/or fraudulent claims, violated laws, and misrepresentations made in order to get claims paid were not subject to reimbursement by Medicare Part D, the state Medicaid programs, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs. The ultimate submission by physicians and pharmacists of false and/or fraudulent claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs was a foreseeable factor in the Government's loss, and a consequence of Solvay's fraudulent schemes. Consequently, the state and the United States Government have suffered substantial damages stemming from improper Luvox, Aceon, and AndroGel prescription costs.

IX. CAUSES OF ACTION

A. Count I - False Claims (31 U.S.C. § 3729(a))

420. Relators reallege and hereby incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

421. As a result of Solvay's off-label marketing scheme, ICD-9 code manipulation,

and kickbacks to physicians to induce them to prescribe Luvox, Aceon, and AndroGel, all of the claims that Solvay caused physicians, pharmacists and third-party payers to submit to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs are false or fraudulent. Solvay knowingly caused such false or fraudulent claims to be presented for payment or approval, in violation of 31 U.S.C. § 3729(a)(1).

422. The United States Government paid the false and/or fraudulent claims.

423. By virtue of the false or fraudulent claims that Solvay knowingly caused to be presented, the United States Government has suffered substantial monetary damages.

B. Count II – False Records or Statements (31 U.S.C. § 3729(a))

424. Relators reallege and hereby incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

454. Solvay knowingly made or used, or caused to be made or used, false records or statements, or omitted material facts (a) to get false or fraudulent claims paid or approved by the Government, or (b) that were material to false or fraudulent claims, in violation of 31 U.S.C. § 3729(a). The false records or statements included, but were not limited to, the false or misleading materials and other statements provided to physicians, DRUGDEX, and the federal and state governments to induce physicians to prescribe high volumes of Luvox, Aceon, and AndroGel, and the physicians' and pharmacists' and third-party payers' false certifications, express and/or implied, and representations of full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute. Physicians, pharmacies, and pharmacists make express and/or implied

certifications in their state Medicaid provider enrollment forms that they will comply with all federal and state laws applicable to Medicaid. The following are representative samples of the types of certifications health care providers make when entering Medicaid Provider Agreements with the State Medicaid programs:

455. When a provider enters into the "Medi-Cal Provider Agreement" with the State of California's Health and Human Services Agency, the provider agrees under the Provider Attestation section that "compliance with the provisions of this agreement is a condition precedent to payment to the provider." Medi-Cal Provider Agreement, Item 40 Provider Attestation, at 8, http://files.medi-cal.ca.gov/pubsdoco/provappsenroll/o2enrollment_DHCS6208.pdf and incorporated herein). The agreement's provisions include the provider's obligation to comply with the California Department of Health Care Services' rules, regulations and provisions found in Chapters 7 and 8 of the Welfare and Institutions Code as well as all federal laws and regulations governing and regulating Medicaid providers. *Id*. at 1, Item 2. Furthermore, the provider agrees not to engage in or commit fraud or abuse including fraud under applicable federal or state laws and abuse that would result in unnecessary costs to health care programs financed in whole or in part by the Federal Government or any state or local agency in California or any other state, or practices that are inconsistent with sound medical practices that result in reimbursement from health care programs financed in whole or in part by the Federal Government or any state or local agency in California or any other state. *Id.* at 3, Item 15. Under Item 19 - Prohibition of Rebate, Refund or Discount, the provider agrees "not to offer, furnish or deliver any rebate, refund, preference…or other gratuitous consideration in connection with the provision of health care services…or to

take any other action or receive any other benefit prohibited by state or federal law." *Id.* at 4, Item 19. Finally, the provider agrees to comply with the Welfare and Institutions Code billing and claims requirements, its implementing regulations and the provider manual. *Id.* at 4, Item 24.

456. The Colorado Medicaid Assistance Program "Provider Participation Agreement" requires the provider to "comply with applicable provisions of the Social Security Act, as amended; federal or state laws, regulations, and guidelines and Department rules." Provider Participation Agreement, Item A – Provider Participation, at 15, http://www.colorado.gov/cs/Satellite/HCPF/HCPF/1197969485906, and incorporated by reference herein. Under Item K, the provider and person signing the claims or submitting electronic claims understand that "[T]he knowing submission of false claims or causing another to submit false claims may subject the persons responsible to criminal charges, civil penalties, and/or forfeitures." *Id.* at 16. Moreover, the "Provider Signature Page" states that by executing Colorado's Provider Agreement, the provider understands "that any false claims, statement, documents, or concealment of material fact may be …prosecuted under applicable federal and state laws." *Id.* at 20.

457. The State of Delaware requires providers to enter into a "Contract for Items or Services Delivered to Delaware Assistance Program Eligibles in the Department of Health and Social Services" with the Department of Health and Social Services, Division of Medicaid and Medical Assistance, Delaware Medical Assistance Program ("DMAP"). By signing the contract, the provider agrees to abide by and comply with DMAP's rules, regulations, policies and procedures as well as the terms of the Social Security Act. Contract for Items or Services

Delivered to Delaware Assistance Program Eligibles in the Department of Health and Social Services, Section 1 Applicable Laws and Regulations, at 1, http://www.dmap.state.de.us/downloads/forms/DMEENROLL.pdf, and incorporated by reference herein. Furthermore, the provider's submission of any claim for payment will constitute certification by the provider that the items and services for which the claim for payment is submitted were in compliance with the DMAP rules, regulations, and policies, including certification that the services were actually provided and medically necessary. *Id.* at 2, Section 3 Payment for Items or Services.

458. A provider who signs the District of Columbia's "Department of Health Medical Assistance Administration Medicaid Provider Agreement" agrees "to satisfy all requirements of the Social Security Act, as amended, and be in full compliance with the standards prescribed by Federal and State standards." Department of Health Medical Assistance Administration Medicaid Provider Agreement, General Provisions C, at 20, https://www.dc-medicaid.com/dcwebportal/docs/providerenrollment/provider_application_2007.pdf, and incorporated by reference herein.

459. The State of Florida's "Medicaid Provider Enrollment Application" must be completed by any person or entity desiring to receive payment for medical, medical-related, and waiver-related services provided to Medicaid recipients. Under Section VII – Certification, of the Application, in order to be eligible to receive direct or indirect payments for services rendered to Florida Medicaid Program recipients, a provider must certify that the provider understands "that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable federal and state laws." Florida Medicaid Provider Enrollment

Application, Section VII Certification, at 9, https://portal.flmmis.com/FLPublic/Portals/0/StaticContent/Public/ENROLLMENT/December%25202004%2520App%2520EDS%2520Web%2520Version%2520062508.pdf, and incorporated herein. Furthermore, Section 409.907 of Chapter 409, Social and Economic Assistance of the Florida Statutes, which governs the Florida Medicaid provider agreements, provides that an individual or entity with a provider agreement in effect will only receive payment for services rendered to Medicaid recipients, if that provider is "performing services or supplying the goods in accordance with federal, state and local laws…." FLA. STAT. § 409.907.

460. In Hawaii, a health care provider signs the "Hawaii State Medicaid Program Provider Agreement and Condition of Participation" and agrees to abide by the applicable provisions of the Hawaii State Medicaid Program as set forth in the Hawaii Administrative Rules, Title 17, Subtitle 12 and the applicable provisions of the Code of Federal Regulations relating to the Medical Assistance Program. Hawaii State Medicaid Program Provider Agreement and Condition of Participation, Section 1, at 5, http://www.med-quest.us/PDFs/Frequently%20Used%20Forms%20for%20Providers/DHS%201139.pdf, and incorporated by reference herein. Additionally, under Part C of the agreement, the provider understands that the provider may be suspended or terminated from participation in the Medicaid program for violations of the provisions of H.A.R. Subtitle 12, Chapter 17-1704 pertaining to Provider Fraud and Chapter 17-1736 pertaining to Provider Provisions. Id. (Part C), at p. 7..

461. Under the Illinois "Agreement for Participation Illinois Medical Assistance Program," a provider who wishes to submit claims for services rendered to eligible Healthcare and Family Services clients agrees, on a continuing basis, to comply with "Federal standards

specified in Title XIX and XXI of the Social Security Act and with all other applicable Federal and State laws and regulations." State of Illinois Department of Healthcare and Family Services Agreement for Participation Illinois Medical Assistance Program, Item 3, at 1, http://www.hfs.illinois.gov/assets/hfs1413.pdf, and incorporated by reference herein. Moreover, the provider agrees "to be fully liable for the truth, accuracy and completeness of all claims submitted…to the Department for payment." *Id.* at 1, Item 6. Additionally, the Provider acknowledges that all services provided will be in compliance with such laws and the applicable provisions of the Illinois Healthcare and Family Services Medical Assistance Program handbooks and that such compliance is "a condition of payment for all claims submitted." *Id.* The provider further agrees that "[A]ny submittal of false or fraudulent claim or claims or any concealment of a material fact may be prosecuted under applicable Federal and State laws." *Id.*

462. When signing the "Indiana Health Coverage Programs Provider Agreement," a provider agrees "to comply with all federal and state statutes and regulations pertaining to the Indiana Health Coverage Programs, as they may be amended from time to time." ICHP Provider Agreement, at 14, Item 2, http://www.indianamedicaid.com/ihcp/ProviderServices/Forms/IHCP%20Pharmacy%20Provider%20Application%20and%20Maintenance%20Form.pdf, and incorporated by reference herein. The provider also understands that "the submission of false claims, statements, and documents or the concealment of material fact may be prosecuted under the applicable federal and/or state laws." *Id.*, at 15, Item 14. Moreover the provider agrees "[A]s a condition of payment…to abide by and comply with all the stipulations, conditions and terms set forth" in the agreement. Id. at p. 17. Furthermore, Indiana regulations state that "A provider who accepts payment of a claim

submitted under the Medicaid program is considered to have agreed to comply with the statutes and rules governing the program." IND. CODE § 12-15-21-1 (2011).

463. The Louisiana Medical Assistance Program Integrity Law (MAPIL), codified in LSA-RS-46:437.1 – 46:440.3, statutorily establishes that the Louisiana Medicaid PE-50 Provider Enrollment Agreement is a contract between the provider and the Louisiana Department of Health and Hospitals. The MAPIL provides that "the department shall make payments from the medical assistance funds…to any person who has a provider agreement with the department and who agrees to comply with all federal and state laws and rules pertaining to the medical assistance programs." LSA-RS-46.437.11A. Additionally, by signing the "PE-50 Addendum-Provider Agreement," the provider certifies that the provider understands all claims paid will be from Federal and State Funds, and any false claims, statements or documents or concealment of fact may be prosecuted under applicable Federal and State laws. PE-50 Addendum – Provider Agreement, at 2, Items 21 and 23, http://www.lamedicaid.com/provweb1/provider_enrollment/Enrollment_Individuals.pdf, and incorporated by reference herein.

464. In Massachusetts, pharmacies sign agreements with MassHealth, the Massachusetts Medicaid program. Massachusetts regulations require "all pharmacies participating in MassHealth [to] comply with the regulations governing MassHealth, including but not limited to MassHealth regulations set forth in 130 CMR 406.00 and 450.00." 130 CMR 406.401. Massachusetts regulations also state that Mass Health will pay for physician services provided to members, "subject to the restrictions and limitations described in the MassHealth regulations." 130 CMR 433.402. MassHealth regulation, 130 CMR 450.261, requires all

providers to comply "with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, specifically including but not limited to 42 U.S.C. § 1320a-7b [the Federal Anti-Kickback Statute]."

465. A provider agreeing to the Minnesota Health Care Program's "Provider Agreement" agrees to "comply with all federal and state statutes and rules relating to the delivery of services to individuals and to the submission of claims for such services." Minnesota Health Care Programs Provider Agreement, at 1, Item 2, https://edocs.dhs.state.mn.us/lfserver/Public/DHS-3535-ENG, and incorporated by reference herein.

466. Under the Montana "Medicaid Provider Enrollment Application", the provider, "IN CONSIDERATION OF MEDICAID PAYMENTS MADE FOR APPROPRIATE MEDICALLY NECESSARY SERVICES RENDERED TO THE ELIGIBLE CLAIMANTS . . . ." agrees to comply with "all applicable laws, rules and written policies pertaining to the Montana Medicaid Program including but not limited to Title XIX of the Social Security Act, the Code of Federal Regulations, Montana Codes Annotated, Administrative Rules of Montana and written Department of Public Health and Human Services policies." Montana Medicaid Provider Enrollment Application, at 4, http://medicaidprovider.hhs.mt.gov/pdf/enrollpacket.pdf, and incorporated by reference herein. Furthermore, the provider understands "THAT PAYMENTS OF CLAIMS WILL BE FROM FEDERAL AND STATE FUNDS AND THAT ANY FALSIFICATION OR CONCEALMENT OF A MATERIAL FACT MAY BE PROSECUTED UNDER FEDERAL AND STATE LAW." *Id.* at 5. Moreover, the Montana regulations require providers to "comply with all applicable state and federal statutes, rules and regulations,

including but not limited to federal regulations and statutes found in Title 42 of the Code of Federal Regulations and the United States Code governing the Medicaid Program and all applicable Montana statutes and rules governing licensure and certification." MONT. ADMIN. R. 37.85.401 (2011).

467. The Magellan Medicaid Administration administers the Nevada Medicaid program on behalf of the state and provides the Provider Enrollment Agreement. Under this agreement the provider is "responsible for the presentation of true, accurate and complete information on all invoices/claims submitted to the Magellan Medicaid Administration." Magellan Medicaid Administration Provider Enrollment Application, Declaration – For all Providers, at 6, https://nevada.fhsc.com/providers/enroll.asp, and incorporated by reference herein. Additionally the provider "understands that payment…of those claims will be from Federal and State funds and that false claims, statements, documents, or concealment of material facts may be prosecuted under applicable Federal and State laws." *Id*. Moreover, the provider also enters the "Nevada Medicaid and Nevada Check Up Provider Contract" with the State of Nevada Division of Health Care Financing and Policy, wherein the Division agrees to only provide payment for services that are "timely claimed, and actually and properly rendered by Provider in accordance with federal and state law and the state policies and procedures set forth in the Medicaid Services Manual, Nevada Check Up Manual and Nevada Medicaid Billing Manual. Other claims are not properly payable Division claims." Nevada Medicaid and Nevada Check Up Provider Contract, Section 2 – Reimbursement, at 2. The provider is made responsible for the validity and accuracy of its claims. *Id.*

468. In New Hampshire, the provider signs the "New Hampshire Medicaid Program Provider Enrollment Agreement" and certifies to "abide by all rules, regulations, billing manuals, and bulletins promulgated by the Department pertaining to the provision of care or services under NH Title XIX and the claiming of payments for those services." New Hampshire Medicaid Program Provider Enrollment Agreement, at 1, http://www.nhmedicaid.com/Downloads/Forms/Provider%20Enrollment%20App%20-%20final04.pdf, and incorporated by reference herein.

469. A provider when signing the New Jersey Department of Health and Senior Services', "Provider Agreement Between New Jersey Department of Health and Senior Service and Provider" agrees "to comply with all applicable State and Federal Medicaid laws and policies, and rules and regulations promulgated pursuant thereto . . . ." and agrees "to comply with Section 1909 of P.L. 92-603, Section 242(c) which makes it a crime for persons found guilty of making any false statement or representation of a material fact in order to receive any benefit or payment under the Medicaid Assistance program . . . ." Provider Agreement Between New Jersey Department of Health and Senior Service and Provider, at 1, Items 1 and 5, http://www.state.nj.us/health/forms/pe-1.pdf, and incorporated by reference herein.

470. When a provider signs the New Mexico "Medical Assistance Division Provider Participation Agreement, the provider "AGREES TO ABIDE BY AND BE HELD TO ALL FEDERAL, STATE, AND LOCAL LAWS, RULES AND REGULATIONS, INCLUDING, BUT NOT LIMITED TO THOSE PERTAINING TO MEDICAID AND THOSE STATED HEREIN." State of New Mexico Human Services Department Medical Assistance Division Provider Participation Agreement, at 6, https://nmmedicaid.acs-

inc.com/nm/pages/static/PDFs/ProvEnrollPacket/MAD335.pdf, and incorporated by reference herein. Furthermore, the New Mexico regulations state that "A provider who furnishes services to a Medicaid eligible recipient agrees to comply with all federal and state laws, regulations, and executive orders relevant to the provision of services." N.M. CODE R. § 8.302.1.11 (2011).

471. Under the New York State Medicaid program's "Physician Request for Enrollment," a provider agrees to "comply with the rules, regulations, and official directives of the Department . . . ." New York State Medicaid Physician Request for Enrollment, at 5, https://www.emedny.org/info/ProviderEnrollment/FFS%20Enrollment%20Packets/CAQH%20Physician%20Enrollment/CAQH%20%20Physician%20Request%20for%20Enrollment.pdf, and incorporated by reference herein.

472. Under North Carolina's "Provider Administrative Participation Agreement," a provider may submit claims to the state Medicaid program either through electronic or paper claims submission process. In consideration for the right to submit paperless claims, the provider agrees to "abide by all Federal and State statutes, rules, regulations and policies…of the Medicaid program . . . ." By submitting electronic claims, the provider agrees that "[A]ny false statement, claims or concealment of or failure to disclose a material fact may be prosecuted under applicable federal and/or state law (P.L. 95-142a and N.C. G.S. 108A-63) . . . ." North Carolina Medicaid Provider Enrollment Agreement, Electronic Claims Submission (ECS) Agreement, at 1, Items 1 and 2, https://www.nctracks.nc.gov/provider/providerEnrollment/LoginAction?SessionIndex=begin,=, and incorporated by reference herein. Additionally, the provider agrees when filing non-electronic Medicaid claims, that "payment of claims will be from federal, state and local tax

funds and any false claims, statements, or documents or concealment of a material fact may be prosecuted under applicable Federal and State laws . . . ." *Id.*

473. The provider entering into the "State of Rhode Island Executive Office of Health and Human Services Provider Agreement Form" agrees to "follow all laws, rules, regulations, certification standards, policies and amendments including but not limited to the False Claims Act, and HIPAA, that govern the Rhode Island Medical Assistance Program as specified by the Federal Government and the State of Rhode Island." State of Rhode Island Executive Office of Health and Human Services Provider Agreement Form, at 1, Item 1, http://www.dhs.ri.gov/Portals/0/Uploads/Documents/Public/MA_Providers/Enrollment/prov_agreement.pdf, and incorporated by reference herein.

474. In Tennessee, a provider enters the State of Tennessee's "Department of Finance and Administration Provider Participation Agreement Medicaid/TennCare Title XIX Program" in order to participate in the Tennessee Medicaid health care program. By signing the agreement, the applicant agrees to, among other things, "comply with all contractual terms and Medicaid policies as outlined in Federal and State rules and regulations and Medicaid provider manuals and bulletins." State of Tennessee The Department of Finance and Administration Provider Participation Agreement Medicaid/TennCare Title XIX Program, at 1, Item 7, http://www.tn.gov/tenncare/forms/mccchoices.pdf, and incorporated by reference herein.

475. In the State of Texas Medicaid Provider Enrollment Application providers certify that "concealment of a material fact, or pertinent omissions may constitute fraud and may be prosecuted under applicable federal and state law." Texas Medicaid Provider Enrollment Application, at 6.5,

http://www.tmhp.com/Provider_Forms/Provider%20Enrollment/Texas%20Medicaid%20Provider%20Enrollment%20Application.pdf, and incorporated by reference herein. Providers further certify that "any falsification, omission, or misrepresentation in connection with…claims filed may result in all paid services declared as an overpayment and subject to recoupment." *Id.* Providers also certify that they will comply with the requirements of the enrollment agreement, including "federal laws and regulations relating to fraud, abuse and waste in health care and the Medicaid program." *Id.* at 6.2, 6.5. The Texas Medicaid enrollment agreement requires signatories to notify the State of Texas if they fall out of compliance with any of their obligations. *Id.*

476. Providers of medical services in the Commonwealth of Virginia, including physicians and pharmacists, must also sign a Participation Agreement. This agreement requires the provider to certify that when participating in the Virginia Medical Assistance Program the "provider agrees to comply with all applicable state and federal laws," including the Health Insurance Portability and Accountability of Act of 1996 and all administrative policies and procedures of the Virginia Medicaid Assistance Program. Commonwealth of Virginia Department of Medical Assistance Services Medical Assistance Program Participation Agreement, at 1, Item 8, https://www.virginiamedicaid.dmas.virginia.gov/wps/PA_VAProviderServices/VAPdfRenderServlet?selectedCode=A50, and incorporated by reference herein.

477. In Wisconsin the "Provider Agreement" is a contract between a provider and the Wisconsin Department of Health Services that sets forth conditions of participation and reimbursement. The provider's signature signifies acknowledgement that any statement or

representation of a material fact made or caused to be made in the application or during the process "for a benefit or payment or made for the use in determining rights to such benefit or payment" that is false as defined by s.49.49(1) or (4m) of the Wisconsin statutes subjects the provider to criminal or other penalties." Wisconsin Medicaid Provider Agreement and Acknowledgement of Terms of Participation, at 3, https://www.forwardhealth.wi.gov/WIPortal/Tab/42/icscontent/pdf/certPackets/physician.pdf.spage, and incorporated by reference herein.

478. In addition, every time they submit an electronic claim for reimbursement by the state Medicaid programs pursuant to an electronic claims submission agreement, physicians and pharmacists also make express and/or implied certifications that they are complying with state and federal laws applicable to the Medicaid program and that there has not been a material omission.

479. Moreover, to participate in Medicare, providers, such as physicians and pharmacists, must first sign enrollment agreements. These agreements require providers to certify that they understand that "payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with . . . the Federal anti-kickback statute." Ex. 143 (Medicare Enrollment Application at 25).

425. Compliance with federal and state laws and regulations was a condition of payment. Each prescription that was written as a result of the Defendants' illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such prescriptions submitted to a federal health insurance program represents a false and/or fraudulent claim for payment.

426. By virtue of the false records or statements that Solvay made or used, the United States Government has suffered substantial monetary damages.

427. Solvay further knowingly caused physicians and pharmacists and third-party payers to make or use false records or statements (a) to get false or fraudulent claims paid or approved by the Government, or (b) material to false or fraudulent claims, in violation of 31 U.S.C. §3729(a).

C. Count III – Conspiracy (31 U.S.C. § 3729(a))

428. Relators reallege and hereby incorporate by reference each and every allegation contained in the preceding paragraphs of this Complaint.

429. Solvay conspired with physicians to promote off-label uses of Luvox, Aceon, and AndroGel in violation of the FCA and to pay kickbacks to physicians in violation of the Anti-Kickback Statute to induce physicians to prescribe high volumes of Luvox, Aceon, and AndroGel, thereby causing all of the physicians' and pharmacists' and third-party payers' claims to the state Medicaid programs, Medicare, CHAMPUS/TRICARE, CHAMPVA, Federal Employees Health Benefit Plan, AIDS Drug Assistance Programs ("ADAPs"), and other federal healthcare programs to be false or fraudulent. Accordingly, Solvay conspired to defraud the Government by (a) getting false or fraudulent claims allowed or paid, or (b) committing a violation of the FCA, in violation of 31 U.S.C. § 3729(a).

430. By virtue of the false or fraudulent claims submitted, paid, or approved as a result of Solvay's conspiracy to defraud the Government, the United States has suffered substantial monetary damages.

D. Count IV - Retaliation (31 U.S.C. § 3730(h))

431. Relators reallege and incorporate by reference each and every allegation

contained in the preceding paragraphs of this Complaint.

432. In violation of the False Claims Act § 3730(h), Solvay took negative employment actions against Relators in response to their investigation and initiation of this claim.

433. As a result of Solvay's conduct, the Relators suffered negative employment consequences and have suffered damages, now and in the future.

RELIEF

436. On behalf of the United States Government, the *qui tam* Relators seek to receive monetary damages equal to three times that suffered by the United States Government. In addition, Relators seek to receive all civil penalties on behalf of the United States Government in accordance with the False Claims Act.

437. The *qui tam* Relators seek to receive on their own behalf, all monetary damages that they are entitled to for Solvay's retaliatory conduct against them. In addition, Relators seek punitive damages on their own behalf.

438. The *qui tam* Relators seek to be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act.

439. The *qui tam* Relators seek to be awarded all costs and expenses for this action, including attorneys' fees and court costs.

440. The *qui tam* Relators seek pre-judgment interest at the highest rate allowed by law.

PRAYER

WHEREFORE, Relators pray that this Court enter judgment on behalf of the Relators and against Solvay for the following:

- Damages in the amount of three (3) time the actual damages suffered by the United States Government as a result of Solvay's conduct;
- Civil penalties against Solvay equal to $11,000 for each violation of 31 U.S.C. § 3729;
- The maximum amount allowed pursuant to 31 U.S.C. § 3730(d);
- All costs and expenses of this litigation, including attorneys' fees and costs of court;
- Relators' individual damages;
- Pre-judgment interest at the highest rate allowed by law for the retaliatory conduct by Solvay;
- Punitive damages to the Relators for the retaliatory conduct by Solvay; and
- All other relief on behalf of the Relators or the United States Government to which they may be entitled and that the Court deems just and proper.

E. Count V - Illinois Whistleblower Reward and Protection Act (740 ILCS *et seq.*)

441. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

442. This is a *qui tam* action brought by Relators and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq*.

443. 740 ILCS 175/3(a) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the State of a member of the Guard a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

444. In addition, 305 ILCS 5/8A-3(b) of the Illinois Public Aid Code (Vendor Fraud and Kickbacks) prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind in return for furnishing any item or service for which payment may be made in whole or in part under the Illinois Medicaid program.

445. Solvay knowingly violated 740 ILCS 175/3(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Illinois from at least 1994 to the present by violating the Illinois Anti-Kickback Statute 305 ILCS 5/8A-3(b) and the Federal Anti-Kickback Act, as described herein.

446. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Illinois Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the Illinois Anti-Kickback Statute (305 ILCS 5/8A-3(b)). Compliance with federal and state laws and regulations was a condition of payment.

447. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

448. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Illinois's payment decision.

449. The ultimate submission by physicians, pharmacies, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Illinois's loss, and a consequence of the scheme.

450. As a result of Solvay's violations of 740 ILCS 175/3(a), the State of Illinois has been damaged.

451. There are no bars to recovery under 740 ILCS 175/4(e)(4), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 740 ILCS 175/4(b) on behalf of themselves and the State of Illinois.

452. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF ILLINOIS:

- Three times the amount of actual damages that the State of Illinois has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Illinois;
- Prejudgment interest; and

- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

F. Count VI - California False Claims Act (Cal. Gov't. Code § 12650 *et seq.*)

453. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

454. This is a *qui tam* action brought by Relators and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

455. Cal. Gov't Code § 12651(a) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;

(c) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(d) knowingly makes, uses, or causes to made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision;

(e) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

456. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal. Bus. & Prof. Code §§ 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

457. Solvay knowingly violated Cal. Gov't Code § 12651(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of California from at least 1994 to the present by violating Cal. Bus. & Prof. Code §§ 650-650.1 and Cal. Welf, & Inst. Code §14107.2 and the Federal Anti-Kickback Act, as described herein.

458. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the California Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute and the California Anti-Kickback Statutes (Cal. Bus. & Prof. Code §§ 650-650.1 and Cal. Welf. & Inst. Code §14107.2). Compliance with federal and state laws and regulations was a condition of payment.

459. The State of California, by and through the California Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

460. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of California's payment decision.

461. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of California's loss, and a consequence of the scheme.

462. As a result of Solvay's violations of Cal. Gov't Code §12651(a), the State of California has been damaged.

463. There are no bars to recovery under Cal. Gov't Code § 12652(d)(3), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of themselves and the State of California.

464. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF CALIFORNIA:

- Three times the amount of actual damages that the State of California has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of up to $10,000 for each false claim that Solvay presented or caused to be presented to the State of California;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

G. Count VII - Florida False Claims Act (Fla. Stat. § 68.081 *et seq.*)

465. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

466. This is a *qui tam* action brought by Relators and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

467. Fla. Stat. § 68.082(2) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

(c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

468. Solvay knowingly violated Fla. Stat. § 68.082(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Florida from at least 1994 to the present by violating of the Federal Anti-Kickback Act and the Florida Anti-Kickback Statute (Fla. Stat. § 409.920), as described herein.

469. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Florida Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians

and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Florida Anti-Kickback Statute (Fla. Stat. § 409.920). Compliance with federal and state laws and regulations was a condition of payment.

470. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, paid the false and/or fraudulent claims.

471. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Florida's payment decision.

472. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Florida's payment decision.

473. As a result of Solvay's violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged.

474. There are no bars to recovery under Fla. Stat. § 68.087(3) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of themselves and the State of Florida.

475. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF FLORIDA:

- Three times the amount of actual damages that the State of Florida has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Florida;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

H. Count VIII – Massachusetts False Claims Act (Mass. Gen. Laws Ann. 12 § 5A *et seq*.)

476. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

477. This is a *qui tam* action brought by Relators and the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. 12 § 5A *et seq.*

478. Mass. Gen. Laws Ann. 12 § 5B provides liability for any person who-

(a) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

(c) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(d) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

479. In addition, Mass. Gen. Laws Ann. 118E § 41 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or overtly, in cash or in kind in return for furnishing any good, service or item for which payment may be made in whole or in part under the Massachusetts Medicaid program.

480. Solvay knowingly violated Mass. Gen. Laws Ann. 12 § 5B and knowingly caused hundreds of thousands of false claims to be made, used and presented to the Commonwealth of Massachusetts from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Massachusetts Anti-Kickback Statute (Mass. Gen. Laws Ann. 118E §41), as described herein.

481. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Massachusetts Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Massachusetts

Anti-Kickback Statute (Mass. Gen. Laws Ann. 118E §41). Compliance with federal and state laws and regulations was a condition of payment.

482. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs paid the false and/or fraudulent claims.

483. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the Commonwealth of Massachusetts's payment decision.

484. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the Commonwealth of Massachusetts's loss, and a consequence of the scheme.

485. As a result of Solvay's violations of Mass. Gen. Laws Ann. 12 § 5B, the Commonwealth of Massachusetts has been damaged.

486. There are no bars to recovery under Mass. Gen. Laws Ann. 12 § 5G(3) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mass. Gen. Laws Ann. 12 § 5C(2) on behalf of themselves and the Commonwealth of Massachusetts.

487. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the COMMONWEALTH OF MASSACHUSETTS:

- Three times the amount of actual damages that the Commonwealth of Massachusetts has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the Commonwealth of Massachusetts;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Mass. Gen. Laws Ann.12, §5F and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

I. Count IX - Tennessee Medicaid False Claims Act (Tenn. Code Ann. § 71-5-181 *et seq*.)

488. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

489. This is a *qui tam* action brought by Relators and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

490. Tenn. Code Ann. § 71-5-182(a)(1) provides liability for any person who-

(a) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

(b) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false; or

(c) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

491. Solvay knowingly violated Tenn. Code Ann. § 71-5-182(a)(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Tennessee from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Tennessee Anti-Kickback Statute (Tenn. Code Ann. § 71-5-182), as described herein.

492. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Tennessee Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and Tennessee Anti-Kickback Statute (Tenn. Code Ann. § 71-5-182). Compliance with federal and state laws and regulations was a condition of payment.

493. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

494. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Tennessee's payment decision.

495. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Tennessee's loss, and a consequence of the scheme.

496. As a result of Solvay's violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged.

497. There are no bars to recovery under Tenn. Code Ann. § 71-5-183(d)(2) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of themselves and the State of Tennessee.

498. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF TENNESSEE:

- Three times the amount of actual damages that the State of Tennessee has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Tennessee;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(d) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

J. Count X - Delaware False Claims and Reporting Act (6 Del. C. § 1201 *et seq*.)

499. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

500. This is a *qui tam* action brought by Relators and the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

501. 6 Del. C. § 1201(a) provides liability for any person who-

(a) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or

(c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

502. In addition, 31 Del. C. § 1005 prohibits the solicitation or receipt of any remuneration (including kickbacks, bribes or rebate) directly or indirectly, overtly or covertly, in cash or in kind in return for the furnishing of any medical care or services for which payment may be made in whole or in part under any public assistance program.

503. Solvay knowingly violated 6 Del. C. § 1201(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Delaware from at least

1994 to the present by violating the Federal Anti-Kickback Act and the Delaware Anti-Kickback Statute (31 Del. C. § 1005), as described herein.

504. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Delaware Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Delaware Anti-Kickback Statute (31 Del. C. § 1005). Compliance with federal and state laws and regulations was a condition of payment.

505. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

506. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Delaware's payment decision.

507. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Delaware's loss, and a consequence of the scheme.

508. As a result of Solvay's violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged.

509. There are no bars to recovery under 6 Del. C. § 1206(c) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and

independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 6 Del. C. § 1203(b) on behalf of themselves and the State of Delaware.

510. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF DELAWARE:

- Three times the amount of actual damages that the State of Delaware has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of Delaware;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to 6 Del. C. § 1205, and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

K. Count XI - Nevada False Claims Act (N.R.S. § 357.010 *et seq*.)

511. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

512. This is a *qui tam* action brought by Relators and the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010 *et seq*.

513. N.R.S. § 357.040(1) provides liability for any person who-

(a) knowingly presents or causes to be presented a false claim for payment or approval;

(b) knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;

(c) conspires to defraud by obtaining allowance or payment of a false claim;

(d) is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

514. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made in whole or in part under the Nevada Medicaid program.

515. Solvay knowingly violated N.R.S. § 357.040(1) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Nevada from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Nevada Anti-Kickback Statute (N.R.S. § 422.560), as described herein.

516. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Nevada Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Nevada Anti-Kickback

Statute (N.R.S. § 422.560). Compliance with federal and state laws and regulations was a condition of payment.

517. The State of Nevada, by and through the Nevada Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

518. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Nevada's payment decision.

519. The ultimate submission by physicians, pharmacists, and third-party payers of false claims to the state Medicaid programs was a foreseeable factor in the State of Delaware's loss, and a consequence of the scheme.

520. As a result of Solvay's violations of N.R.S. § 357.040(1), the State of Nevada has been damaged.

521. There are no bars to recovery under N.R.S. § 357.100 and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.R.S. § 357.080 on behalf of themselves and the State of Nevada.

522. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF NEVADA:

- Three times the amount of actual damages that the State of Nevada has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Nevada;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

L. Count XII - Louisiana Medical Assistance Programs Integrity Law (La. Rev. Stat. Ann. § 46:437.1 *et seq.*)

523. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

524. This is a *qui tam* action brought by Relators and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann. § 46:437.1 *et seq.*

525. La. Rev. Stat. Ann. § 46:438.3 provides-

(a) No person shall knowingly present or cause to be presented a false or fraudulent claim;

(b) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds; and

(c) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

526. In addition, La. Rev. Stat. Ann. § 46:438.2(A) prohibits the solicitation, receipt, offering or payment of any financial inducements, including kickbacks, bribes, rebates, etc., directly or indirectly, overtly or covertly, in cash or in kind, for furnishing health care goods or services paid for in whole or in part by the Louisiana medical assistance programs.

527. Solvay knowingly violated La. Rev. Stat. Ann. § 46:438.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Louisiana from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Louisiana Anti-Kickback Statute (La. Rev. Stat. Ann. § 46:438.2(A)), as described herein.

528. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Louisiana Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Louisiana Anti-Kickback Statute (La. Rev. Stat. Ann. § 46:438.2(A)). Compliance with federal and state laws and regulations was a condition of payment.

529. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

530. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Louisiana's payment decision.

531. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Louisiana's loss, and a consequence of the scheme.

532. As a result of Solvay's violations of La. Rev. Stat. Ann. § 46:438.3 the State of Louisiana has been damaged.

533. There are no bars to recovery under La. Rev. Stat. Ann. § 46:439.1(E) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to La. Rev. Stat. Ann. § 46.439.1(A) on behalf of themselves and the State of Louisiana.

534. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF LOUISIANA:

- Three times the amount of actual damages that the State of Louisiana has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Louisiana;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to La. Rev. Stat. § 46:439.4(A) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorney's fees and costs; and
- Such further relief as this Court deems equitable and just.

M. Count XIII - Hawaii False Claims Act (Haw. Rev. Stat. § 661-21 *et seq*.)

535. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

536. This is a *qui tam* action brought by Relators and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq*.

537. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(c) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; or

(d) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

538. Solvay knowingly violated Haw. Rev. Stat. § 661-21(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Hawaii from

at least 1994 to the present by violating the Federal Anti-Kickback Act and the Hawaii Anti-Kickback Statute (Haw. Rev. Stat. § 346-43.5), as described herein.

539. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Hawaii Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Hawaii Anti-Kickback Statute (Haw. Rev. Stat. § 346-43.5). Compliance with federal and state laws and regulations was a condition of payment.

540. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

541. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Hawaii's payment decision.

542. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid programs was a foreseeable factor in the State of Hawaii's loss, and a consequence of the scheme.

543. As a result of Solvay's violations of Haw. Rev. Stat. § 661-21(a) the State of Hawaii has been damaged.

544. There are no bars to recovery under Haw. Rev. Stat. § 661-28 and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with

direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of themselves and the State of Hawaii.

545. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF HAWAII:

- Three times the amount of actual damages that the State of Hawaii has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Hawaii;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

N. Count XIV - District of Columbia Procurement Reform Amendment Act (D.C. Code § 2-308.13 *et seq*.)

546. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

547. This is a *qui tam* action brought by Relators and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

548. D.C. Code § 2-308.14(a) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;

(c) conspires to defraud the District by getting a false claim allowed or paid by the District;

(d) is the beneficiary of an inadvertent submission of a false claim to the District, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the District.

549. Solvay knowingly violated D.C. Code § 2-308.14(a) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the District of Columbia from at least 1994 to the present by violating the Federal Anti-Kickback Act and the District of Columbia Anti-Kickback Statute (D.C. Code § 4-802), as described herein.

550. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the District of Columbia Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the District of Columbia Anti-Kickback Statute (D.C. Code § 4-802). Compliance with federal and state laws and regulations was a condition of payment.

551. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

552. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the District of Columbia's payment decision.

553. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid programs was a foreseeable factor in the District of Columbia's loss, and a consequence of the scheme.

554. As a result of Solvay's violations of D.C. Code § 2-308.14(a), the District of Columbia has been damaged.

555. There are no bars to recovery under D.C. Code § 2-308.15(c)(2) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of themselves and the District of Columbia.

556. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the DISTRICT OF COLUMBIA:

- Three times the amount of actual damages that the District of Columbia has sustained as a result of Solvay's fraudulent and illegal practices;

- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the District of Columbia;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

O. Count XV - Virginia Fraud Against Taxpayer Act (Va. Code Ann. § 8.01-216.1 *et seq.*)

557. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

558. This is a *qui tam* action brought by Relators and the Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayer Act, Va. Code Ann. § 8.01-216.1 *et seq.*

559. Va. Code Ann. § 8.01-216.3 provides liability for any person who-

(a) Knowingly presents, or causes to be presented, to an officer or employee of the Commonwealth false or fraudulent claim for payment or approval;

(b) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Commonwealth;

(c) Conspires to defraud the Commonwealth by getting a false or fraudulent claim allowed or paid;

(d) Has possession, custody, or control of property or money used, or to be used, by the Commonwealth and, intending to defraud the Commonwealth

or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate or receipt;

(e) Authorizes to make or deliver a document certifying receipt of property used, or to be used by the Commonwealth, and intending to defraud the Commonwealth, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(f) Knowingly buys or receives as a pledge of an obligation or debt, public property from an officer or employee of the Commonwealth who lawfully may not sell or pledge the property; or

(g) Knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Commonwealth.

560. Solvay knowingly violated Va. Code Ann. § 8.01-216.3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the Commonwealth of Virginia from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Virginia Anti-Kickback Statute (Va. Code Ann. § 32.1-315), as described herein.

561. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Virginia Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Virginia Anti-Kickback Statute (Va. Code Ann. § 32.1-315). Compliance with federal and state laws and regulations was a condition of payment.

562. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

563. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the Commonwealth of Virginia's payment decision.

564. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the Commonwealth of Virginia's loss, and a consequence of the scheme..

565. As a result of Solvay's violations of Va. Code Ann. § 8.01-216.3, the Commonwealth of Virginia has been damaged.

566. There are no bars to recovery under Va. Code Ann. § 8.01-216.8, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Va. Code Ann. § 8.01-216.5 on behalf of themselves and the Commonwealth of Virginia.

567. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the COMMONWEALTH OF VIRGINIA:

- Three times the amount of actual damages that the Commonwealth of Virginia has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the Commonwealth of Virginia;

- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Va. Code Ann. § 8.01-216.7 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

P. Count XVI -Georgia State False Medicaid Claims Act (Ga. Code. Ann. § 49-4-168 *et seq*.)

568. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

569. This is a *qui tam* action brought by Relators and the State of Georgia to recover treble damages and civil penalties under the Georgia State False Medicaid Claims Act, Ga. Code. Ann. § 49-4-168 *et seq*.

570. Ga. Code. Ann. § 49-4-168.1(a) provides liability for any person who-

(a) knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;

(c) conspires to defraud the Georgia Medicaid program by getting a false or fraudulent claim allowed or paid.

571. Solvay knowingly violated Ga. Code. Ann. § 49-4-168.1 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Georgia

from at least 1994 to the present by violating the Federal Anti-Kickback Act, as described herein.

572. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Georgia Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

573. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

574. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Georgia's payment decision.

575. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Georgia's loss, and a consequence of the scheme.

576. As a result of Solvay's violations of Ga. Code. Ann. § 49-4-168.1, the State of Georgia has been damaged.

577. There are no bars to recovery under Ga. Code Ann. § 49-4-168.2(j)(2) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Ga. Code Ann. § 4-4-168.2(b) on behalf of themselves and the State of Georgia.

578. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF GEORGIA:

- Three times the amount of actual damages that the State of Georgia has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of Georgia;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Ga. Code. Ann. § 49-4-168.2(i)(2) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

Q. Count XVII - Indiana False Claims and Whistleblower Protection Act (Ind. Code § 5-11-5.5-1 *et seq*.)

579. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

580. This is a *qui tam* action brought by Relators and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims and Whistleblower Protection Act, Ind. Code § 5-11-5.5-1 *et seq*.

581. Ind. Code § 5-11-5.5-2 provides liability for any person who-

(b) Knowingly or intentionally:

(1) presents a false claim to the state for payment or approval;

(2) makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

(3) with intent to defraud the state, delivers less money or property to the state than the amount recorded on the certificate or receipt the person receives from the state;

(4) with intent to defraud the state, authorizes issuance of a receipt without knowing that the information on the receipt is true;

(5) receives public property as a pledge of an obligation on a debt from an employee who is not lawfully authorized to sell or pledge the property;

(6) makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state;

(7) causes or induces another person to perform an act described in subdivisions (1) through (6).

582. Solvay knowingly violated Ind. Code § 5-11-5.5-2 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Indiana from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Indiana Anti-Kickback Statute (Ind. Code § 12-15-24-2), as described herein.

583. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Indiana Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Indiana Anti-Kickback

Statute (Ind. Code § 12-15-24-2). Compliance with federal and state laws and regulations was a condition of payment.

584. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

585. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Indiana's payment decision.

586. The ultimate submission by physicians, pharmacists, and third-party payers of false claims to the state Medicaid programs was a foreseeable factor in the State of Indiana's loss, and a consequence of the scheme.

587. As a result of Solvay's violations of Ind. Code § 5-11-5.5-2 the State of Indiana has been damaged.

588. There are no bars to recovery under Ind. Code § 5-11-5.5-7(f) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Ind. Code § 5-11-5.5-4 on behalf of themselves and the State of Indiana.

589. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF INDIANA:

- Three times the amount of actual damages that the State of Indiana has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 for each false claim that Solvay caused to be presented to the State of Indiana;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Ind. Code § 5-11-5.5-6 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

R. Count XVIII - Michigan Medicaid False Claims Act (Mich. Comp. Laws § 400.601 *et seq*.)

590. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

591. This is a *qui tam* action brought by Relators and the State of Michigan to recover treble damages and civil penalties under the Michigan Medicaid False Claims Act, Mich. Comp. Laws § 400.601 *et seq*.

592. Mich. Comp. Laws §§ 400.603 to 400.607 provides liability for a person who-

(a) knowingly makes or causes to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit;

(b) knowingly makes or presents or causes to be made or presented to an employee or officer of this state claim under Medicaid;

(c) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim.

593. Solvay knowingly violated Mich. Comp. Laws §§ 400.603 to 400.607 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Michigan from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Michigan Anti-Kickback Statute (Mich. Comp. Laws § 400.604), as described herein.

594. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Michigan Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Michigan Anti-Kickback Statute (Mich. Comp. Laws § 400.604). Compliance with federal and state laws and regulations was a condition of payment.

595. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

596. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Michigan's payment decision.

597. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Michigan's loss, and a consequence of the scheme.

598. As a result of Solvay's violations of Mich. Comp. Laws §§ 400.603 to 400.607 the State of Michigan has been damaged.

599. There are no bars to recovery under Mich. Comp. Laws § 400.610(13) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mich. Comp. Laws § 400.610a on behalf of themselves and the State of Michigan.

600. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF MICHIGAN:

- Three times the amount of actual damages that the State of Michigan has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty equal to the full amount received for each false claim that Solvay caused to be presented to the State of Michigan;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Mich. Comp. Laws § 400.610a and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

S. Count XIX - Montana False Claims Act (Mont. Code Ann. § 17-8-401 *et seq*.)

601. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

602. This is a *qui tam* action brought by Relators and the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq*.

603. Mont. Code Ann. § 17-8-403 provides liability for any person causing damages in excess of $ 500 to a governmental entity for any of the following acts:

(a) knowingly presenting or causing to be presented to an officer or employee of the governmental entity a false claim for payment or approval;

(b) knowingly making, using, or causing to be made or used a false record or statement to get a false claim paid or approved by the governmental entity;

(c) conspiring to defraud the governmental entity by getting a false claim allowed or paid by the governmental entity.

604. Solvay knowingly violated Mont. Code Ann. § 17-8-403 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Montana from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Montana Anti-Kickback Statute (Mont. Code Ann § 45-6-313), as described herein.

605. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Montana Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Montana Anti-Kickback Statute (Mont. Code Ann § 45-6-313). Compliance with federal and state laws and

regulations was a condition of payment.

606. The State of Montana, by and through the Montana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

607. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Montana's payment decision

608. The ultimate submission by physicians, pharmacists, and third-party payers of false claims to the state Medicaid programs was a foreseeable factor in the State of Montana's loss, and a consequence of the scheme.

609. As a result of Solvay's violations of Mont. Code Ann. § 17-8-403 the State of Montana has been damaged.

610. There are no bars to recovery under Mont. Code Ann. § 17-8-403(5)(c) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mont. Code Ann. § 17-8-406 on behalf of themselves and the State of Montana.

611. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF MONTANA:

- Three times the amount of actual damages that the State of Montana sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty pursuant Mont. Code Ann. § 17-8-410 to for each false claim that Solvay caused to be presented to the State of Montana
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Mont. Code Ann. § 17-8-410 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

T. Count XX - New Hampshire False Claims Act (N.H. Rev. Stat. Ann. § 167:61 *et seq*.)

612. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

613. This is a *qui tam* action brought by Relators and the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire False Claims Act, N.H. Rev. Stat. Ann. § 167:61 *et seq*.

614. N.H. Rev. Stat. Ann. § 167:61-b(I) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the department, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the department;

(c) conspires to defraud the department by getting a false or fraudulent claim allowed or paid.

615. Solvay knowingly violated N.H. Rev. Stat. Ann. § 167:61-b(I) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Hampshire from at least 1994 to the present by violating the Federal Anti-Kickback Act, as described herein.

616. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the New Hampshire Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

617. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

618. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of New Hampshire's payment decision.

619. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of New Hampshire's loss, and a consequence of the scheme.

620. As a result of Solvay's violations of N.H. Rev. Stat. Ann. § 167:61-b(I), the State of New Hampshire has been damaged.

621. There are no bars to recovery under N.H. Rev. Stat. Ann. § 167:61-e(III)(d) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.H. Rev. Stat. Ann. § 167:61-c(II)(a) on behalf of themselves and the State of New Hampshire.

622. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF NEW HAMPSHIRE:

- Three times the amount of actual damages that the State of New Hampshire has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of New Hampshire;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to N.H. Rev. Stat. Ann. § 167:61-e and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

U. Count XXI –New Jersey False Claims Act (N.J. Stat. Ann. §§ 2A:32-C1–2A:32-C18)

623. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

624. This is a *qui tam* action brought by Relators and the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32-C1–2A:32-C18.

625. N.J. Stat. Ann. § 2A:32C-3 provides liability for any person who-

(a) knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

626. Solvay knowingly violated N.J. Stat. Ann. § 2A:32C-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Jersey from at least 1994 to the present by violating the Federal Anti-Kickback Act, as described herein.

627. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the New Jersey Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

628. The State of New Jersey, by and through the New Jersey Medicaid program and

other state health care programs, paid the false and/or fraudulent claims.

629. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of New Jersey's payment decision.

630. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of New Jersey's loss, and a consequence of the scheme.

631. As a result of Solvay's violations of N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey has been damaged.

632. There are no bars to recovery under N.J. Stat. Ann. § 2A:32C-9(c), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.J. Stat. Ann. § 2A:32C-5(b) on behalf of themselves and the State of New Jersey.

633. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF NEW JERSEY:

- Three times the amount of actual damages that the State of New Jersey has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of New Jersey;

- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to N.J. Stat. Ann. § 2A:32C-3**7** and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

V. Count XXII - New Mexico Medicaid False Claims Act (N.M. Stat. Ann. § 27-14-1 *et seq*.)

634. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

635. This is a *qui tam* action brought by Relators and the State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq*. and the New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §c 44-9-1 *et seq*.

636. N.M. Stat. Ann. § 27-14-4 provides liability for any person who-

(a) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;

(b) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;

(c) makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

(d) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent.

637. N.M. Stat. Ann. § 44-9-3 provides liability for any person who –

(a) presents, or causes to be presented, to the state a claim for payment to an employee, officer or agent of the state or to a contractor, grantee or other recipient of state funds knowing that such claim is false or fraudulent;

(b) knowingly makes or uses, or causes to be made or used, a false, misleading or fraudulent record to obtain or support the approval of or the payment on a false or fraudulent claim;

(c) knowingly makes or uses, or causes to be made or used, a false, misleading or fraudulent record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property the state;

(d) conspires to defraud the state by obtaining approval or payment on a false or fraudulent claim;

(e) conspires to make, use, or cause to be made or used, a false, misleading, or fraudulent record or statement to conceal, avoid or decrease an obligation to pay to transmit money or property to the state.

638. Solvay knowingly violated N.M. Stat. Ann. § 27-14-4 and § 44-9-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New Mexico from at least 1994 to the present by violating the Federal Anti-Kickback Act and the New Mexico Anti-Kickback Statute (N.M. Stat Ann. § 30-44-7), as described herein.

639. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the New Mexico Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the New Mexico

Anti-Kickback Statute (N.M. Stat Ann. § 30-44-7). Compliance with federal and state laws and regulations was a condition of payment.

640. The State of New Mexico, by and through the New Mexico Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

641. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of New Mexico's payment decision.

642. The ultimate submission by physicians, pharmacists, and third-party payers of false claims to the state Medicaid programs was a foreseeable factor in the State of New Mexico's loss, and a consequence of the scheme.

643. As a result of Solvay's violations of N.M. Stat. Ann. § 27-14-4 and § 44-9-3, the State of New Mexico has been damaged.

644. There are no bars to recovery under N.M. Stat. Ann. § 27-14-10(C) and § 44-9-7(A)(2), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.M. Stat. Ann. § 27-14-7(B) and § 44-9-5(A) on behalf of themselves and the State of New Mexico.

645. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF NEW MEXICO:

- Three times the amount of actual damages that the State of New Mexico has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty for each false claim that Solvay caused to be presented to the State of New Mexico;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to N.M. Stat. Ann. § 27-14-9 and § 44-9-7 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

W. Count XXIII - New York False Claims Act (N.Y. State Fin. Law § 187 *et seq*.)

646. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

647. This is a *qui tam* action brought by Relators and the State of New York to recover treble damages and civil penalties under the New York False Claims Act, N.Y. State Fin. Law § 187 *et seq*.

648. N.Y. State Fin. Law § 189 provides liability for any person who-

(a) knowingly presents, or causes to be presented, to any employee, officer or agent of the state or a local government, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or a local government;

(c) conspires to defraud the state or a local government by getting a false or fraudulent claim allowed or paid.

649. Solvay knowingly violated N.Y. State Fin. Law § 189 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of New York from at least 1994 to the present, by violating the Federal Anti-Kickback Act, as described herein.

650. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the New York Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

651. The State of New York, by and through the New York Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

652. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of New York's payment decision.

653. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of New York's loss, and a consequence of the scheme.

654. As a result of Solvay's violations of N.Y. State Fin. Law § 189, the State of New York has been damaged.

655. There are no bars to recovery under N.Y. Fin. Law § 190(9) and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.Y. State Fin. Law § 190(2) on behalf of themselves and the State of New York.

656. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF NEW YORK:

- Three times the amount of actual damages that the State of New York has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $6,000 and not more than $12,000 for each false claim that Solvay caused to be presented to the State of New York;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to N.Y. State Fin. Law § 190(6) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

X. Count XXIV– Oklahoma Medicaid False Claims Act (Okla. Stat. Ann. § 5053.1 *et seq.*)

657. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

658. This is a *qui tam* action brought by Relators and the State of Oklahoma to recover treble damages and civil penalties under 63 Okla. Stat. Ann. § 5053.1 *et seq*.

659. 63 Okla. Stat. Ann. § 5053.1(B) provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the State of Oklahoma, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(c) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

660. Solvay knowingly violated 63 Okla. Stat. Ann. § 5053.1(B) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Oklahoma from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Oklahoma Anti-Kickback Statute (56 Okla. Stat. Ann. § 1005), as described herein.

661. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Oklahoma Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Oklahoma Anti-Kickback Statute (56 Okla. Stat. Ann. § 1005). Compliance with federal and state laws and regulations was a condition of payment.

662. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

663. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Oklahoma's payment decision.

664. The ultimate submission by physicians, pharmacies, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Oklahoma's loss, and a consequence of the scheme.

665. As a result of Solvay's violations of 63 Okla. Stat. Ann. § 5053.1(B), the State of Oklahoma has been damaged.

666. There are no bars to recovery under 63 Okla. Stat. Ann. § 5053.5 and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 63 Okla. Stat. Ann. § 5053.2 on behalf of themselves and the State of Oklahoma.

667. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF OKLAHOMA:

- Three times the amount of actual damages that the State of Oklahoma has sustained as a result of Solvay's fraudulent and illegal practices;

- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Oklahoma;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to 63 Okla. Stat. Ann. § 5053.4 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

Y. Count XXV - Rhode Island State False Claims Act (R.I. Gen. Laws § 9-1.1-1 *et seq*.)

668. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

669. This is a *qui tam* action brought by Relators and the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq*.

670. R.I. Gen. Laws § 9-1.1-3 provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(c) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

671. Solvay knowingly violated R.I. Gen. Laws § 9-1.1-3 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Rhode

Island from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Rhode Island Anti-Kickback Statutes (R.I. Gen Laws 5-48.1-3 and 40-8.2-3), as described herein.

672. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Rhode Island Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Rhode Island Anti-Kickback Statutes (R.I. Gen Laws 5-48.1-3 and 40-8.2-3). Compliance with federal and state laws and regulations was a condition of payment.

673. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

674. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Rhode Island's payment decision.

675. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Rhode Island's loss, and a consequence of the scheme.

676. As a result of Solvay's violations of R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island has been damaged.

677. There are no bars to recovery under R.I. Gen. Laws § 9-1.1-4(e)(3), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with

direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to R.I. § 9-1.1-4(b) on behalf of themselves and the State of Rhode Island.

678. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF RHODE ISLAND:

- Three times the amount of actual damages that the State of Rhode Island has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Solvay caused to be presented to the State of Rhode Island;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-4(d) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

Z. COUNT XXVI - TEXAS FALSE CLAIMS ACT **(V.T.C.A. Hum. Res. Code § 36.001 *et seq.*)**

679. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

680. This is a *qui tam* action brought by Relators and the State of Texas to recover double damages and civil penalties under Texas False Claims Act, V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

681. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who -

(a) knowingly makes causes to be made a false statement or misrepresentation of a material fact to permit a person to receive a benefit or payment under the Medicaid Program that is not authorized or that is greater than the benefit or payment that is authorized;

(b) knowingly makes, causes to be made, induces, or seeks to induce the making of a false statement or misrepresentation of material fact concerning . . . information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(c) knowingly enters into an agreement, combination, or conspiracy to defraud the state by obtaining or aiding another person in obtaining an unauthorized payment or benefit from the Medicaid program or a fiscal agent;

(d) knowingly makes, uses, or causes the making or use of a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to this state under the Medicaid program; or

(e) knowingly engages in conduct that constitutes a violation under V.T.C.A Hum. Res. Code § 32.039 (the Texas Anti-Kickback Statute).

682. Solvay knowingly violated V.T.C.A. Hum. Res. Code § 36.002 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Texas from at least 1994 to the present by violating the Federal Anti-Kickback Act and the Texas Anti-Kickback Statute.

683. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Texas Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians

and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Texas Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

684. The State of Texas, by and through the Texas Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

685. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Texas's payment decision.

686. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Texas's loss, and a consequence of the scheme.

687. As a result of Solvay's violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged.

688. There are no bars to recovery under V.T.C.A. Hum. Res. Code § 36.113(b), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of themselves and the State of Texas.

689. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF TEXAS:

- The amount of actual damages that the State of Texas has sustained as a result of Solvay's fraudulent and illegal practices;
- Three times the amount of actual damages that the State of Texas has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,000 as described in V.T.C.A. Hum. Res. Code Section 36.052(a)(3) for each false claim that Solvay caused to be presented to the state of Texas;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code Section 36.110, and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action; and
- An award of reasonable attorneys' fees and costs.

AA. Count XXVII - Wisconsin False Claims Act

690. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

691. This is a *qui tam* action brought by Relators and the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims Act, Wis. Stat. Ann. § 20.931 *et seq.*

692. Wis. Stat. Ann. § 20.931(2) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

693. Solvay knowingly violated Wis. Stat. Ann. § 20.931(2) and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Wisconsin from at least 1994 to the present by violating the Federal Anti-Kickback Statute, as described herein.

694. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Wisconsin Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

695. The State of Wisconsin, by and through the State of Wisconsin Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

696. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Wisconsin's payment decision.

697. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Wisconsin's loss, and a consequence of the scheme.

698. As a result of Solvay's violations of Wis. Stat. Ann. § 20.931(2), the State of Wisconsin has been damaged.

699. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Wis. Stat. Ann. §20.931 on behalf of themselves and the State of Wisconsin.

700. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF WISCONSIN:

- Three times the amount of actual damages that the State of Wisconsin has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of Wisconsin;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Wis. Stat. Ann. § 20.931(11) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;

- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

BB. Count XXVIII- Colorado False Claims Act

701. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

702. This is a *qui tam* action brought by Relators and the State of Colorado to recover treble damages and civil penalties under the Colorado False Claims Act, Col. Rev. Stat. Ann. § 25.5-4-304 *et seq.*

703. Col. Rev. Stat. Ann. §25.5-4-305 provides liability for any person who

(a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(c) conspires to commit a violation of §25.5-4-305;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State of Colorado, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State of Colorado.

704. Solvay knowingly violated Col. Rev. Stat. Ann. § 25.5-4-305 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Colorado from at least 1994 to the present by violating the Federal Anti-Kickback Statute, as described herein.

705. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Colorado Medicaid program are false or fraudulent. Further, Solvay knowingly caused

physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

706. The State of Colorado, by and through the Colorado Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

707. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Colorado's payment decision.

708. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Colorado's loss, and a consequence of the scheme.

709. As a result of Solvay's violations of Col. Rev. Stat. Ann. § 25.5-4-305, the State of Colorado has been damaged.

710. There are no bars to recovery under Col. Rev. Stat. Ann. §25.5-4-306, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Col. Rev. Stat. Ann. §25.5-4-306(2) on behalf of themselves and the State of Colorado.

711. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Colorado in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF COLORADO:

- Three times the amount of actual damages that the State of Colorado has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of Colorado;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Col. Rev. Stat. Ann. § 25.5-4.306 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

CC. Count XXIX - Connecticut Act Implementing the Provisions of the Budget Concerning Human Services and Making Changes to Various Social Services Statutes

712. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

713. This is a *qui tam* action brought by Relators and the State of Connecticut to recover treble damages and civil penalties under the Connecticut Act Implementing the Provisions of the Budget Concerning Human Services and making Changes to Various Social Services Statutes, Conn. Pub. Act No. 09-5.

714. Conn. Pub. Act No. 09-5, § 2 provides liability for any person who:

(a) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval under medical assistance programs administered by the Department of Social Services;

(b) knowingly makes, uses or causes to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services;

(c) conspires to defraud the state by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state under medical assistance programs administered by the Department of Social Services.

715. Solvay knowingly violated Conn. Pub. Act. No. 09-5, § 2 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Connecticut from at least 1994 to the present by violating the Federal Anti-Kickback Statute, as described herein.

716. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Connecticut Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute and the Connecticut laws prohibiting kickbacks (Conn. Gen Stat. §§ 53a-161c, 53a-161d). Compliance with federal and state laws and regulations was a condition of payment.

717. The State of Connecticut, by and through the Connecticut Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

718. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Connecticut's payment decision.

719. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Connecticut's loss, and a consequence of the scheme.

720. As a result of Solvay's violations of Conn. Pub. Act No. 09-5, § 2, the State of Connecticut has been damaged.

721. There are no bars to recovery under Conn. Pub. Act No. 09-5, § 9, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Conn. Pub. Act No. 09-5, §4(a) on behalf of themselves and the State of Connecticut.

722. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Connecticut in the operation of the medical assistance programs administered by the Connecticut Department of Social Services.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF CONNECTICUT:

- Three times the amount of actual damages that the State of Connecticut has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of Connecticut;

- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Conn. Pub. Act No. 09-5, § 6(b) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

DD. Count XXX - Maryland False Claims Act

723. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

724. This is a *qui tam* action brought by Relators and the State of Maryland to recover treble damages and civil penalties under the Maryland False Claims Act, Md. Code Ann. §2-601 *et seq.*

725. Md. Code Ann. §2-602 provides liability for any person who

(a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(c) conspires to commit a violation of §2-602;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State of Maryland, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State of Maryland.

726. Solvay knowingly violated Md. Code Ann. §2-602 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Colorado from at least 1994 to the present by violating the Federal Anti-Kickback Statute, as described herein.

727. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Maryland Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

728. The State of Maryland, by and through the Maryland Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

729. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Maryland's payment decision.

730. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Maryland's loss, and a consequence of the scheme.

731. As a result of Solvay's violations of Md. Code Ann. §2-602, the State of Maryland has been damaged.

732. There are no bars to recovery under Md. Code Ann. §2-606, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with

direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Md. Code Ann. §2-604(a) on behalf of themselves and the State of Maryland.

733. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Maryland in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF MARYLAND:

- Three times the amount of actual damages that the State of Maryland has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of Maryland;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Md. Code Ann. §2-602 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

EE. Count XXXI- Minnesota False Claims Act

734. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

735. This is a *qui tam* action brought by Relators and the State of Minnesota to recover treble damages and civil penalties under the Minnesota False Claims Act, Minn. Stat. Ann. §15C.01 *et seq.*

736. Minn. Stat. Ann. § 15C.02 provides liability for any person who

(a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(c) conspires either to present a false or fraudulent claim to the state for payment or approval or to make, use, or cause to made or used a false record or statement to obtain payments or approval of a false or fraudulent claim;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the State of Minnesota.

737. Solvay knowingly violated Minn. Stat. Ann. §15C.02 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Colorado from at least 1994 to the present by violating the Federal Anti-Kickback Statute, as described herein.

738. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the Minnesota Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

739. The State of Minnesota, by and through the Minnesota Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

740. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of Minnesota's payment decision.

741. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of Minnesota's loss, and a consequence of the scheme.

742. As a result of Solvay's violations of Minn. Stat. Ann. §15C.02, the State of Minnesota has been damaged.

743. There are no bars to recovery under Minn. Stat. Ann. §15C.05, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Minn. Stat. Ann. §15C.01 on behalf of themselves and the State of Minnesota.

744. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Minnesota in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF MINNESOTA:

- Three times the amount of actual damages that the State of Minnesota has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of Minnesota;

- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Minn. Stat. Ann. §15C.13 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

FF. Count XXXII - North Carolina False Claims Act

745. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

746. This is a *qui tam* action brought by Relators and the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. §1-605 *et seq.*

747. N.C. Gen. Stat. § 1-607 provides liability for any person who

(a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(c) conspires to commit a violation of § 1-607;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State of North Carolina, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State of North Carolina.

748. Solvay knowingly violated N.C. Gen. Stat. §1-607 and knowingly caused hundreds of thousands of false claims to be made, used and presented to the State of Colorado from at least 1994 to the present by violating the Federal Anti-Kickback Statute, as described herein.

749. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the North Carolina Medicaid program are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

750. The State of North Carolina, by and through the North Carolina Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

751. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the State of North Carolina's payment decision.

752. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the state Medicaid program was a foreseeable factor in the State of North Carolina's loss, and a consequence of the scheme.

753. As a result of Solvay's violations of N.C. Gen. Stat. §1-607, the State of North Carolina has been damaged.

754. There are no bars to recovery under N.C. Gen. Stat. §1-611, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with

direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.C. Gen. Stat. §1-608(b) on behalf of themselves and the State of North Carolina.

755. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the STATE OF NORTH CAROLINA:

- Three times the amount of actual damages that the State of North Carolina has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the State of North Carolina;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to N.C. Gen. Stat. §1-610 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

GG. Count XXXIII- City of Chicago False Claims Act

756. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

757. This is a *qui tam* action brought by Relators and the City of Chicago to recover treble damages and civil penalties under the City of Chicago False Claims Act, Municipal Code of Chicago §1-22-010 *et seq.*

496. Municipal Code of Chicago §1-22-020 provides liability for any person who

> (e) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
>
> (f) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> (g) conspires to get a false or fraudulent claim paid or approved by the city;
>
> (h) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the City of Chicago.

758. Solvay knowingly violated Municipal Code of Chicago §1-22-020 and knowingly caused false claims to be made, used and presented to the City of Chicago from at least 1994 to the present by violating the Federal Anti-Kickback Statute, as described herein.

759. As a result of Solvay's off-label marketing and kickback schemes, all of the claims that Solvay knowingly caused physicians and pharmacists to knowingly submit to the City of Chicago are false or fraudulent. Further, Solvay knowingly caused physicians and pharmacists to falsely certify, expressly and/or impliedly, and represent full compliance with all federal and state laws and regulations prohibiting fraudulent acts and false reporting, including but not limited to the Federal Anti-Kickback Statute. Compliance with federal and state laws and regulations was a condition of payment.

760. The City of Chicago paid the false and/or fraudulent claims.

761. Given the structure of the health care systems, the false statements, representations, and records made by Solvay had the potential to influence the City of Chicago's payment decision.

762. The ultimate submission by physicians, pharmacists, and third-party payers of false and/or fraudulent claims to the City of Chicago was a foreseeable factor in the City of Chicago's loss, and a consequence of the scheme.

763. As a result of Solvay's violations of Municipal Code of Chicago, the City of Chicago has been damaged.

764. There are no bars to recovery under Municipal Code of Chicago §1-22-030, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Municipal Code of Chicago on behalf of themselves and the City of Chicago.

765. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the City of Chicago.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Solvay:

To the CITY OF CHICAGO:

- Three times the amount of actual damages that the City of Chicago has sustained as a result of Solvay's fraudulent and illegal practices;
- A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Solvay caused to be presented to the City of Chicago;
- Prejudgment interest; and

- All costs incurred in bringing this action.

To RELATORS:

- The maximum amount allowed pursuant to Municipal Code of Chicago §1-22-030 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

HH. Count XXXIV –Common Fund Relief

766. Relators repeat and reallege each allegation contained in the preceding paragraphs of this Complaint.

767. While the states possessing *qui tam* statutes have a regulatory scheme for rewarding the Relators for coming forward, those which have none will potentially receive a windfall with little or no investigation or commitment of time or resources to the recovery. The Common Fund doctrine preserves the right of the litigant or counsel to an award from the Common Fund generated. The United States Supreme Court, and many others, have addressed this situation. *Boeing Company v. Van Gemert*, 444 U.S. 472 478 (1980):

> Since the decisions in *Trustees v. Greenough*, 105 U.S. 527, 26 L.Ed. 1157 (1882), and *Central Railroad & Banking Co. v. Pettuss*, 113 U.S. 116, 5 S.Ct. 387, 28 L.Ed. 915 (1885), this Court has recognized consistently that a litigant or a lawyer who recovers a common fund for the benefit of persons other than himself or his client is entitled to a reasonable attorney's fee from the fund as a whole. [citations omitted]. The common-fund doctrine reflects the traditional practice in courts of equity, *Trustees v. Greenough*, supra 105 U.S., at 532-537, and it stands as a well-recognized exception to the general principle that requires every litigant to bear his own attorney's fees [citations omitted]. The doctrine rests upon the perception that persons who obtain the benefit of the lawsuit without contributing to its cost are unjustly enriched at the successful litigant's expense [citation omitted]. Jurisdiction over the fund involved in the litigation allows a court to prevent this inequity by assessing attorney's fees against the

> entire fund, thus spreading fees proportionally among those benefitted by this suit. [citations omitted].

Accord, In re Smithkline Beckman Corp. Securities Litig., 751 F. Supp. 525, 531 (E.D. Pa. 1990). There are a huge string of cases which recognize the Common Fund doctrine for situations like that in this case. *See* "The Common Fund Doctrine: Coming of Age in the Law of Insurance Subrogation," 31 Ind. L. Rev. 313, 337-38 (1998). Relators respectfully request this Court to award them a percentage share from the Common Fund generated by their actions.

X. DEMAND FOR JURY TRIAL

768. Pursuant to Federal Rule of Civil Procedure 38, Relators demand a trial by jury.

WHEREFORE, Relators respectfully request all relief described herein.

Dated November 22, 2011

Respectfully submitted,

BERG & ANDROPHY

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CERTIFICATE OF SERVICE

On November 22, 2011, a copy of Relators' Fifth Amended Complaint has been delivered via the Southern District of Texas's CM/ECF system to Mr. Diesenhaus, to the U.S. Attorney's office in the Southern District of Texas, to the Department of Justice in Washington, D.C., and to the Attorney General offices of the States of California, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oklahoma, Rhode Island, Tennessee, Texas, Wisconsin, the Commonwealths of Massachusetts and Virginia, and the District of Columbia. Copies have also been delivered to the states of Connecticut, North Carolina, Colorado, Maryland, and Minnesota.

/s/Sarah M. Frazier